

## **EJP RD**

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# **Del D2.24**

## **Fourth Analysis of national state of play and alignment process with EJP RD**

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## Executive summary

In the framework of Work Package 2 (WP2) “Integrative research and innovation strategy” a specific activity of Task 2.5 (T2.5) “Translation/impact of prioritization on national and European (EU) strategies” has been the periodical assessment of the alignment status of national rare disease (RD) undertakings with the actions promoted by the four Pillars of the European Joint Programme on Rare Diseases (EJP RD). A dedicated survey developed to perform this analysis has been spread in years 2020, 2021 and 2023 to the EJP RD participating countries and to other/associated countries, and was addressed to representatives of the National Mirror Groups (NMGs), if constituted, or to other persons involved in relevant national RD activities. A special attention has been given to specific needs, obstacles and advancements of the European-13 Countries (EU-13 Countries).<sup>1</sup>

The survey, titled “National Plans and Strategies for Rare Diseases”, focused on the existence and state of National Plans and Strategies for rare diseases (NP/NS for RD), as key instruments to face common and specific RD challenges, and on the alignment status of the NP/NS for RD, and of other relevant RD initiatives, with the activities promoted by the four EJP RD Pillars.

In the present deliverable (D), an analysis has been performed on the answers submitted by the twenty-five countries that participated to the 2023 edition of the survey. Moreover, a follow-up analysis has been performed comparing the answers submitted by the nineteen countries that participated both in the 2023 edition of the survey and in one or more of the editions 2020/2021.

These results allowed to draw a status quo of the alignment reached in five years of activity of the EJP RD in 2023, and helped to describe the evolution of the matching faced by the countries participating in EJP RD with the projects' activities over the years. This information figures therefore as feedback for the actions undertaken by the EJP RD until March 2023, suggesting the areas in which the project activities have had more impacts, as well as the fields that need additional efforts. The suggestions will serve to inform the activities of the final actions of the EJP RD and to guide the proposals for forthcoming RD actions.

## Highlights and next actions

- This final report shows the alignment status of the 25 countries that participated to the last edition of the survey “National Plans and Strategies for Rare Diseases” (20 EU and 5 Other/Associated countries). This data contributes to outline the alignment situation of the national RD undertakings with the four EJP RD Pillars' initiatives at month (M) 51 of the EJP RD.
- The main attention is given in this document to the comparisons between the answers submitted by the 19 countries that participated both to the 2023 and to one or more of the editions 2020/2021 of the survey. These comparisons helped in tracking the evolution of the alignment status of these countries over the years.

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<sup>1</sup> Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia

- The emerged results can be taken as hints to identify the areas in which the countries most aligned with the EJP RD undertakings, and those for which the matching with the EJP RD activities has unfolded to a lower extent.
- The conclusions gathered by these analyses can serve as suggestions to recognise best practices and still open challenges after 51 months of activity of the EJP RD.
- Considering the answers submitted to the 2023 edition of the survey, it appears that the national policies for which there seem to be globally a greater alignment with the EJP RD actions are, in the order, those related to “Capacity building and Empowerment” (Pillar 3) and to “Resources and services to foster research on rare diseases”, even if in a lower rate regarding the support to FAIR (Findable, Accessible, Interoperable and Reusable) data (Pillar 2).
- The national RD actions that showed a general lower alignment with the EJP RD activities are primarily those related to “Accelerated translation of research projects and improvement of outcomes of clinical studies” (Pillar 4) and then those related to “National and International Investments on research in the field of RD” (Pillar 1).
- With regard to the EU-13 Countries, the alignment status with the four EJP RD Pillars is in line with the alignment observed when considering all responding countries, with Pillar 3 and 2 (in the order) registering the higher alignment and Pillar 4 and 1 the lowest alignment rate.
- Taking into account the comparisons between the results obtained in 2023 vs 2020/2021 for the countries that participated to the survey in both these reference periods, it can be observed that there have been improvements in the alignment in specific areas of Pillar 1, 2 and 4 (in the order), and that Pillar 3 seems to maintain the highest level of alignment over the years.
- On the other hand, the initiatives for which there have been less positive changes or decrease in the support by the national RD actions appear to be in specific areas of Pillar 4, Pillar 2 and of Pillar 1 (in the order), with a certain loss also in respect to Pillar 3.
- Looking at the focus on the EU-13 Countries, the areas in which there have been major improvements in respect to the development, improvement and translation of RD research results are “Language” and “Lack of options for exploitation of research results”, while “Funding” and “Difficulties in accessing to national resources for funding research and development of RD projects” kept and even increased their criticality. In respect to the improvements in the participation to EU/international projects in the RD field, the “Lack of information on funding opportunities”, the “Limited links to potential partners” and the “Irrelevance of programme topics to own research agenda” have been highlighted, whereas the “Bureaucratic application on responding procedures” and the “Quality of support provided by national contact points” have been pointed as growing obstacles.
- Overall, the results of the comparisons appear encouraging, as the main improvements have been registered in the areas that emerged as critical

points in all editions of the survey (namely in the activities falling under Pillar 4 first, and Pillar 1, as well as in the promotion of FAIR data for Pillar 2), indicating that the national and international RD efforts are progressing in a positive way. Encouraging hints have been highlighted also towards some EU-13 Countries specific needs and obstacles.

- The results have been presented at the “Second Strategic Workshop with national policy makers” that was held on 5 July 2023 in Brussels, as hybrid event, and will be made available to Pillar Leaders as feedback on the work done in the timeframe January 2019-March 2023, and as hints for future RD initiatives, also beyond the EJP RD.

## Introduction and Objective

The development of the research and innovation strategy represented one of the key actions through the duration of the EJP RD to assure a sustainable and efficient definition of the EJP RD annual plans and to continuously develop and tailor the long-term strategy of the project. This pivotal activity has been implemented for the whole duration of the project by the work carried out in WP2 “Integrative research and innovation strategy”, among other, and its Tasks (Task T2.1<sup>2</sup>, T2.2<sup>3</sup>, T2.3<sup>4</sup>, T2.4<sup>5</sup> and T2.5<sup>6</sup>), under the umbrella of the Pillar 0 activities.

The present document represents the final outcome of the work carried out in T2.5 “Translation/impact of prioritization on National and EU strategies”, in respect to the periodical collection of information from EU MS on relevant/complementary RD actions performed at national level, via a specific survey targeting ideally NMGs, and/or key persons deeply involved in the RD policies and actions of their country. EU-13 countries have received a dedicated focus in these series of analysis, for what concerns their specific needs, obstacles and advancements.

The data provided by the participating countries in the three surveys launched in years 2020, 2021 and 2023 allowed to draw an assessment of the alignment occurred during the progression of the project between the EJP RD activities and the RD undertakings at national and EU level. This assessment is of particular relevance for the activities of WP 2 since, from a strategic point of view, the European dimension of the EJP RD and the involvement of the Policy Board were expected to have impact both on the unfolding of the project itself and on the local and European RD context.

This deliverable intends to present and discuss the results collected via the survey “National Plans and Strategies for Rare Diseases” launched in February 2023, and to compare the results with the outputs collected in the previous editions, so to draw an assessment of the alignment status of the national and transnational RD initiatives with the EJP RD activities and to carry out a follow-up. As for D2.23 “Third Analysis of national state of play and alignment process with EJP RD”, the results and conclusions have been presented at the occasion of the Strategic Workshop with relevant policy stakeholders held in July 2023 in Brussels (hybrid event), back to back to the Policy Board and Executive Committee meetings.

The previous editions of the report regarding the analysis of national state of play and alignment with EJP RD activities served as one of the inputs for the elaboration of the confidential Summary Documents on mapped research and innovation needs (R&I needs) produced in Task 2.2, and for their reformulation in the series of public Scoping Papers to be transmitted to the leaders of Task 2.3, 2.4 and 2.5 for complementary actions.

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<sup>2</sup>Task 2.1 Prioritization scheme for EJP RD actions

<sup>3</sup>Task 2.2 Mapping the research and innovation needs (R&I)

<sup>4</sup>Task 2.3 Scientific programming of joint transnational calls

<sup>5</sup> Task 2.4: Management of the medium, longer-term research strategy questions and dedicated linkage with Task Forces of the International RD Research Consortium (IRDIRC)

<sup>6</sup>Translation/impact of prioritization on national and EU strategies

This last deliverable, based on the new collected data and on the wrap-up and synthesis of the previously collected information, will whereas no longer provide information for the mapping of R&I needs of the EJP RD, but constitutes an overview document for a final review of the achievements reached in the translation of the prioritisation strategy at national and EU level. Furthermore, potential areas of interventions for the forthcoming RD initiatives could be hypothesised.

The results discussed in this deliverable will contribute to: (i) deepen the understanding of the alignment status occurred between the national RD policies and the EJP RD actions, (ii) identify the achievements and critical issues faced by the countries in respect to the activities linked with the major actions of the EJP RD, (iii) suggest specific actions to be implemented nationally and internationally, in order to extend the intensions started by the EJP RD in further activities (iv) focus on the specific challenges encountered by the EU-13 Countries for more tailored actions to be promoted.

## Background

The outputs produced along the five-year duration of the project under T2.5, constitute the main background for the present deliverable<sup>7</sup>. It has to be pointed out that the background of the present document encompasses also the WP2 series of Mapped R&I needs, reformulated in the series of Scoping Papers<sup>8</sup>, and the First Report from the strategic workshop with national policy makers<sup>9</sup>.

The background and premises encompassing the “soft-law documents” and initiatives that in the past years were dedicated to stimulate the countries to adopt NP/NS for RD as key instrument for the progressing in the diagnosis, treatment and care for people with RD, have been already described in the “First-“and “Second Analysis of national state of play and alignment process with EJP RD”, and will not be further presented.

## Methodology

A wrap up of the results emerging in the documents cited in the above background has been undertaken. Furthermore, the new data acquired via the survey “National Plans and Strategies for Rare Diseases” launched in February 2023 have been analysed.

An additional review has been performed as follow-up, comparing the answers submitted by the countries that participated to two or more editions of the survey. For this comparison the answers furnished in the 2023 edition have been taken as reference and matched with the most updated data available for the countries from the surveys 2020 and 2021.

Finally, broad conclusions involving all listed inputs have been outlined.

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<sup>7</sup>[D2.21 “First analysis of national state of play and alignment process with EJP RD”](#); [D2.22 “Second analysis of national state of play and alignment process with EJP RD”](#); [D2.23 “Third analysis of national state of play and alignment process with EJP RD”](#)

<sup>8</sup>D2.8 “First Scoping Paper”; D2.9 “Second Scoping Paper”; D2.10 “Third Scoping Paper”; “D2.11 Fourth Scoping Paper”

<sup>9</sup>[D2.25 “First Report from strategic workshop with national policy makers”](#)

## The survey

All the surveys of this series of data collection were composed of multiple-choice questions and open questions, divided into different sections:

- GDPR (General Data Protection Regulation) section
- Section on general information on the person/officer completing the survey (for further follow-up if necessary and for updates in the forthcoming editions of the survey)
- Section on information linked to the areas of interest of the 4 non-transversal Pillars (Pillar 1-4) of the EJP RD, specifically dedicated to analysing the alignment of the NP/NS for RD with the actions promoted by EJP RD. The titles and areas of interest of the 4 Pillars are as follows: "Pillar 1: National and International Investments on research in the field of rare diseases", "Pillar 2: Resources and Services to foster research on rare diseases", "Pillar 3: Capacity building and Empowerment", and "Pillar 4: Accelerated translation of research projects and improvement of outcomes of clinical studies"
- Section on information linked to the areas of interest of the 4 non-transversal Pillars (Pillar 1-4) of the EJP RD, specifically dedicated to analysing the alignment of other national initiatives than the NP/NS in the RD field with the actions promoted by EJP RD. The titles of the areas of interest of the 4 Pillars are as above. As described formerly, it has been decided to ask separate questions regarding the NP/NS for RD and other relevant national RD undertakings in the surveys 2021 and 2023, while in the 2020 edition some questions did not make the distinction if the initiatives were promoted by the NP/NS for RD or by other relevant national activities
- Section dedicated to the EU-13 Countries, and investigating their main perceived obstacles and barriers for the development, improvement and translation of RD research results, as well as for their participation in EU/International projects
- A final open question inviting the respondents to give free comments on aspects regarding the RD field not considered in the survey.

The edition 2023 of the survey included also three multiple-choice questions to assess the impact of the EJP RD on national RD undertakings in terms of: actions not implemented or deemed so far in the country; in terms of the establishment and/or implementation of data repositories and tools for research on RD; and in terms of the establishment of RD trainings.

A further open question asked to describe the most significant changes in the RD area occurred in the country since 2019.

The surveys of years 2020 and 2021 can be found in the dedicated Annexes of D2.22 and D2.23.

The survey of year 2023 is available in Annex 1 of the present document.



### **Privacy issues and delivery platform**

The surveys “National Plans and Strategies for Rare Diseases” are GDPR compliant (EU Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and of the free movement of such data). The launching of the surveys and the gathering of data have been carried out for the first survey via the LisyLime Survey Platform of the Institute National de la Santé et de la Recherche Médicale (INSERM), whereas the following editions via the Forms Microsoft Teams Platform of the EJP RD.

### **Target and timing of the survey**

The main targets of the surveys have been the NMGs as key actors for identifying, discussing and bringing the national needs to the upper level. To date, the NMGs have not been constituted in most countries (in part due to the difficult interactions during the COVID-19 pandemic). For this reason, a refined list of contacts has been created by the Coordination Team (based also on previous similar experiences in the RD field) and the 2.5 Task Leaders, for the distribution of the survey among persons directly/indirectly involved in the NP/NS for RD in the EJP RD countries (and broadly among contacts in the EU MS<sup>10</sup>). It is to note that the surveys invited the respondents that might not have been directly involved in the NP/NS for RD to indicate contact persons directly involved/ more involved in the development or implementation of the NP/NS for RD, as a deep knowledge of the situation in the country was advisable to respond.

The survey edition of 2020 was available on the LisyLime Survey Platform from September to November, while the survey edition 2021 remained open on the Microsoft Teams Platform of the EJP RD on May and June. The survey edition 2023 has been spread on February and remained open until March on the Microsoft Teams Platform of the EJP RD.

The surveys have been distributed via email to EUROPLAN contacts, Orphanet-INSERM contacts and EJP RD Partners. Between the launching and the deadline periods the contacted persons have been periodically asked if assistance in completing the survey was needed.

## **Results**

### **Summary of the results emerged in the previous edition of this series of deliverables**

The “First Analysis of national state of play and alignment process with EJP RD” has been based on the most updated sources of information on the national state of play on RD undertakings, and on a review of documents published by RD-ACTION, IRDiRC and EUROPLAN and on specific publications. After deep discussion with Task Partners, and in the absence of constituted NMGs, it has been agreed to target the analysis on the existing literature and resources and to postpone the collection of data via a dedicated survey to the subsequent years of the project. Focus has

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<sup>10</sup> Cyprus is not participating in EJP RD but has been contacted as EU-13 Country

therefore been set on the “soft-law documents” and initiatives that were dedicated up to 2018 to stimulate the countries to adopt NP/NS for RD as key instruments for the progressing in the diagnosis, treatment and care for people with RD.

Regarding the adoption of NP/NS for RD the following results have been underlined:

- by the time of the delivery of RD-ACTION Overview Report of 2018, 25 countries had adopted a NP/NS for RDs at some stage and 19 of these countries adopted NP/NS which were time-bound (Austria, Bulgaria, Croatia, Czech Republic, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Portugal, Romania, Slovak Republic, Slovenia)
- among the countries that adopted time-bound NP/NS 13 appeared to have apparently still active NP/NS by July 2018 (Austria, Croatia, Czech Republic, Estonia, France, Hungary, Ireland, Luxembourg, Netherlands, Portugal, Romania, Slovak Republic, Slovenia), but that some of them were approaching the end by 2020
- and 6 countries adopted time-bound NP/NS which had expired by July of 2018 and seemed not to have been replaced/renewed (Bulgaria, Finland, Greece, Italy, Latvia, Lithuania)
- the remaining 6 countries adopted NP/NS which appeared to be “ongoing” in 2018 (Belgium, Cyprus, Denmark, Germany, Spain, UK)
- 3 EU MS appeared not to have adopted a NP/NS by the end of 2018: Poland, Malta and Sweden.
- by 2018 also Switzerland and Norway had a RD plan or strategy.

As conclusions it has been stated that the renewal of the focus on NP/NS for RD in Europe was a priority at the time of the delivery of the document, and that there was great heterogeneity in the state of advancement of national policies, and NP/NS for RD.

In the “Second Analysis of national state of play and alignment process with EJP RD”, the results of the first edition of the survey “National Plans and Strategies for Rare Diseases” (launched between September and November 2020) have been analysed and the need to continue progressing in the evaluation of both the impact and the implementation status of the national policies for RD was reaffirmed. The main identified needs regarding the alignment process with the EJP RD Pillars have been: (i) the promotion of RD national and transnational calls for research projects, with a dedicated attention to the national level, and the support of investments to share knowledge (Pillar1); (ii) the constitution of dedicated RD advisory bodies for Research and Innovation and the attention to FAIR data; (iii) trainings on FAIR data, to be addressed especially by the NP/NS for RD (Pillar 3); (iv) reinforce the promotion of both the rapid translation of research results in clinical studies and healthcare, and of the development of innovative methodologies tailored for clinical trials (Pillar 4).

Regarding the EU-13 Countries, difficulties and barriers for the development, improvement and translation of RD research results have been highlighted together with the needs to enhance the participation in EU/International projects in the RD field. The areas that resulted to require more interventions have been the access to “Funding”, the possibilities of “Exploitation of research results at national level”, the

“Links to potential partners”, the assistance on “Bureaucratic application on funding procedures” and the “Quality of support provided by national contact points”.

The second edition of the survey “National Plans and Strategies for Rare Diseases” (launched between May and June 2021) gave the possibility to the 21 countries participating in the 2020 edition to furnish updates and collected inputs from further seven countries. For the four countries that did not give updates, the data collected in 2020 have been still considered valid, given the short laps of time incurred between the two editions of the survey.

The key points emerged from this second analysis can be summarised as the needs to: (i) support investments to share knowledge on RD research activities and to dedicate an attention to the promotion of national calls for research projects, especially in EU-13 Countries (Pillar 1); (ii) the constitution of dedicated RD advisory bodies for Research and Innovation and the attention to FAIR data to be reinforced within the NP/NS for RD (Pillar 2); (iii) trainings on FAIR data and an overall attention for an alignment with RD trainings (Pillar 3); (iv) foster the rapid translation of research results in clinical studies and healthcare and the development of innovative methodologies tailored for clinical trials, particularly in EU-13 Countries (Pillar 4).

For the EU-13 Countries the most relevant fields that needed to be faced to overcome the main perceived obstacles and barriers for the progress, improvement and translation of RD research results, have been identified as “Funding”, “Difficulties in accessing to national resources for funding of research and development of RD projects”, “Lack of options for exploitation of research results at national level” (named in order by decreasing frequency). Other relevant obstacles and barriers to be addresses for the participation in EU/international projects in the RD field were “Limited links to potential partners”, “Lack of information on funding opportunities”, “Bureaucratic application of funding procedures” (in decreasing frequency).

Overall, the results seemed to confirm the main critical points already highlighted by the first data collection, as well as the gaps to be filled to fulfil a good alignment with the proposals of the EJP RD. The detected open challenges and the corresponding suggested actions to face them have been summarised in D2.23 “Second Analysis of national state of play and alignment process with EJP RD” and are consultable at the following LINK.

## Results of the survey 2023

### General information

In 2023, thirty six countries have been reached by the survey (Armenia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Croatia, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, The Netherlands, Turkey, UK), hence 100% of the EJP RD countries, and Cyprus.

Twenty-five of the contacted countries (69%) submitted a completed survey in this last edition (Austria, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, France, Georgia, Germany, Israel, Italy, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Switzerland, The Nether-

lands). Of these, ten are EU-13 Countries (Bulgaria, Cyprus, Czech Republic, Estonia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia), representing 77% of this specific target of the survey.

Eleven of the contacted countries (31%) did not reply to this edition of the survey (Armenia, Belgium, Finland, Greece, Ireland, Sweden, Turkey, UK) of which three are EU-13 Countries (Croatia, Hungary and Latvia).

Six countries missing in the previous editions joined the 2023 survey (Cyprus, Denmark, Malta, Norway, Slovenia, Switzerland).

Below the answers given to each item of the survey by the participating countries have been summarised and briefly described, as done in the previous deliverables. The percentages have been rounded to reach 100% for each item, except for the multiple-choice questions<sup>11</sup>.

**Is there an approved National Plan/Strategy for rare diseases (NP/NS for RD) in your Country?**

<b>A NP/NS for RD has been developed and is under approval in my country, 2 countries (8%):</b> Italy <sup>12</sup> , Malta
<b>Yes, but the approved NP/NS for RD is not active, 1 country (4%):</b> Poland
<b>Yes, but the NP/NS for RD of my country expired and is not under renewal*, 3 countries (12%):</b> Bulgaria, Czech Republic, Estonia
<b>Yes, the NP/NS for RD of my country expired, and a renewed version is under development*, 5 countries (20%):</b> Cyprus, France, Lithuania, Portugal, Serbia
<b>Yes, the NP/NS for RD of my country has been approved and is in force, 11 countries (44%):</b> Austria, Denmark <sup>13</sup> , Germany, Luxembourg <sup>14</sup> , Norway, Romania, Slovakia, Slovenia, Spain, Switzerland, The Netherlands <sup>15</sup>
<b>No, but a NP/NS for RD is under development in my country, 2 countries (8%):</b> Canada, Georgia
<b>No (4%), 1 country:</b> Israel <sup>16</sup>
<b>I don't know: -</b>

Globally, 24 countries (96%) have a NP/NS for RD that is either active, approved but not active, expired, under renewal, under approval or under development.

Eleven countries (44%) declare that a NP/NS for RD has been approved and is in force (Austria, Denmark, Germany, Luxembourg, Norway, Romania, Slovakia, Slovenia, Spain, Switzerland, The Netherlands), and one country (4%) that the NP/NS for RD has been approved but is not in force (Poland).

In eight countries (32%) the NP/NS for RD expired (Bulgaria, Cyprus, Czech Republic, Estonia, France, Lithuania, Portugal, Serbia), and in five of these (20%) a renewed version is under development (Cyprus, France, Lithuania, Portugal, Serbia). The other three countries (12%) reply that the expired NP/NS for RD is not under renewal (Bulgaria, Czech Republic, Estonia). Furthermore, two countries (8%) answer that the

<sup>11</sup> In the present document rounding may have led to some differences in the percentages referring to the same number of countries for the need to adapt the percentages to 100%

<sup>12</sup> Italy is in the process of approval of the second edition of the NP/NS for RD

<sup>13</sup> The plan seems to have expired in 2019

<sup>14</sup> The plan seems to have expired in 2022

<sup>15</sup> The plan seems to have expired in 2018

<sup>16</sup> In the 2020 and 2021 editions of the survey replied that a NP was under development

NP/NS for RD has been developed and is under approval (Italy, Malta), with one country (4%) in the process of approving the first edition (Malta), and one country (4%) the second edition (Italy).

Finally, two countries (8%) declare that a NP/NS for RD is under development (Canada, Georgia), while one country (4%) that there is no NP/NS for RD (Israel).

Among the countries that declare to have an active NP/NS for RD at the time of the data collection, 3 countries seem to have an expired NP/NS for RD (Denmark, Luxembourg, The Netherlands). Further on these countries declare to have adopted one single edition of NP/NS for RD, whose actions might therefore be in force, despite the formal expiry of the Plan or Strategy.

**\*Please specify when the NP/NS for RD expired**

**Table 1. Year of expiry of the NP/NS for RD of the countries declaring to have an expired NP/NS for RD in 2023**

Bulgaria	The previous NP for RD in Bulgaria officially expired on December 31, 2013
Cyprus	The NP/NS expired in 2018, a revision process started in 2019 but this process did not conclude
Czech Republic	2020
Estonia	No data available from the survey
France	2022
Lithuania	National plan for rare diseases, adopted in 2012, does not have a time frame, but it was accompanied by a list of measures for the period of 2013-2017
Portugal	2021
Serbia	On 31 December 2022

The countries with an expired NP/NS for RD have been asked when the NP/NS for RD expired (Table 1). In two countries (22% of the countries with an expired NP/NS for RD) the NP/NS for RD expired in 2022 (France, Serbia), in one country (13%) in 2021 (Portugal), in one country (13%) in 2020 (Czech Republic), in one country (13%) in 2018 (Cyprus), and in one country (13%) in 2013 (Bulgaria). One country (13%) does not reply to this question (Estonia), and one country (13%) specifies that even though having answered to have an expired NP/NS for RD, the NP for RD adopted in 2012 is not provided by a time-frame, while the list of measures that accompanied the NP had the term of 2013-2017 (Lithuania).

One of the countries whose expired NP/NS for RD is not under renewal (33%) describes the main obstacles to the renewal as related with the lack of leadership and points the limited success of the implementation of the expired Plan as linked with the lack of appropriate funding (Bulgaria). The other two countries (67%) do not specify eventual obstacles for the renewal of their expired NP/NS for RD.

When considering the date of approval of the first NP/NS for RD (Table 2), one country (5%) indicates 2004 (France), two countries (10%) 2008 (Bulgaria, Portugal), one country (5%) 2009 (Spain), one country (5%) 2010 (Czech Republic), one country (5%) 2011 (Slovenia), three countries (13%) 2012 (Cyprus, Lithuania, Slovakia), three coun-

tries (13%) 2013 (Germany, Italy, The Netherlands), four countries (19%) 2014 (Denmark, Estonia, Romania, Switzerland), one country (5%) 2015 (Austria), one country (5%) 2018 (Luxembourg), one country (5%) 2019 (Serbia), two countries (10%) 2021 (Norway, Poland).

**Table 2. Year of approval of the NP/NS for RD.<sup>17</sup>**

<b>2004</b>	France
<b>2008</b>	Bulgaria, Portugal
<b>2009</b>	Spain
<b>2010</b>	Czech Republic
<b>2011</b>	Slovenia
<b>2012</b>	Cyprus, Lithuania, Slovakia
<b>2013</b>	Germany, Italy, The Netherlands
<b>2014</b>	Denmark, Estonia, Romania, Switzerland
<b>2015</b>	Austria
<b>2018</b>	Luxembourg
<b>2019</b>	Serbia
<b>2021</b>	Norway, Poland

**How many editions of the NP/NS for RD has your country adopted by now?**

<b>One edition, 14 countries (63%):</b> Austria, Bulgaria, Cyprus, Denmark, Estonia, Germany, Italy, Lithuania, Luxembourg, Norway, Poland, Serbia, Switzerland, The Netherlands
<b>Two editions, 5 countries (23%):</b> Portugal, Romania, Slovakia, Slovenia, Spain
<b>Three editions, 2 countries (9%):</b> Czech Republic, France
<b>First edition under approval, 1 country (5%):</b> Malta

Fourteen countries (67%) adopted one edition of the NP/NS for RD (Austria, Bulgaria, Cyprus, Denmark, Estonia, Germany, Italy, Lithuania, Luxembourg, Norway, Poland, Serbia, Switzerland, The Netherlands) and five countries (23%) two editions (Portugal: 2008; 2015, Romania: 2014; 2021, Slovakia: 2012; 2021, Slovenia: 2011; 2021, Spain: 2009; 2014). Two countries (9%) adopted three editions (Czech Republic: 2012; 2015; 2018, France: 2004; 2011; 2018), and one country (5%) is in the process of approval of its first NP/NS for RD (Malta). It must be pointed out that Czech Republic and Lithuania have both one edition of NP/NS for RD and several action plans/lists of measures provided by timeframes, but according to the survey, Czech Republic declares three editions of NS for RD, and Lithuania one edition of NP for RD with several list of measures. The NS for RD of Czech Republic has a time frame (2010-2020) and is currently expired, while the NP for RD of Lithuania is not time-bound. Czech Republic furthermore highlights that due to Covid-19 and other national priorities, follow-up plans have not been officially implemented. Spain highlights that the content of the NS for RD of the Spanish National Health System (NHS) was evaluated three years

<sup>17</sup> The year refers to the first approval; the table includes the active and expired NP/NS for RD; the percentages refer to the 21 countries with a NP/NS for RD active, expired, under development or first approval (if at the second edition)

after its approval, with an update of the objectives in 2013. These outcomes are reported in Table 3.

**Table 3. Number of editions and year of approval of the NP/NS for RD per country**

Austria	2015
Bulgaria	2008
Cyprus	2012
Czech Republic	2010, with 3 National Action Plans (2012, 2015, 2018) until 2020
Denmark	2014
Estonia	2014
France	2004 first edition, 2011 second edition, 2018 third edition
Germany	2013
Italy	2013 first edition, second edition under approval
Lithuania	2012, with list of measures for the period of 2013-2017
Luxembourg	2018
Malta	First edition under approval
Norway	2021
Poland	2021
Portugal	2008 first edition, 2015 second edition
Romania	2014 first edition, 2021 second edition
Serbia	2019
Slovakia	2012 first edition, 2021 second edition
Slovenia	2011 first edition, 2022 second edition
Spain	2009 first edition, with an evaluation of the content in 2012, and an update of the objectives in 2013; 2014 second edition
Switzerland	2014
The Netherlands	2013

**Is there a periodical evaluation of the NP/NS for RD in your country?<sup>18</sup>**

**Yes, 13 countries (65%):** Austria, Cyprus, Denmark, France, Lithuania, Luxembourg, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, The Netherlands

**No, 7 countries (35%):** Bulgaria, Czech Republic, Estonia, Germany, Norway, Poland, Switzerland

Among the 20 countries asked whether a periodical evaluation of the NP/NS for RD is performed, thirteen (65%) answer in the affirmative (Austria, Cyprus, Denmark, France, Lithuania, Luxembourg, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, The Netherlands), and seven (35%) that there is no periodical evaluation.

**Are you directly involved in the implementation or development of the NP/NS for RD of your country?**

**Yes, 21 countries (88%):** Austria, Bulgaria, Canada, Cyprus, Czech Republic, Den-

<sup>18</sup> On this item data are missing for Italy and Malta, as these countries are in the process of approval of the NP/NS for RD, respectively of their second and first edition. The question has been addressed to the 20 countries declaring to have a NP/NS for RD, active, approved but not active or expired. For Italy this data is missing for the first NP/NS for RD

mark, Estonia, France, Georgia, Germany, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, The Netherlands

**No, 3 countries (12%):** Italy, Lithuania, Switzerland

21 surveys (88%) have been filled by country representatives directly involved in the implementation or development of the NP/NS for RD, and 3 surveys (12%) by country representatives not directly involved.

[Alignment status of NP/NS for RD with the activities promoted by the 4 EJP RD Pillars<sup>19</sup>](#)

The following results show the responses given by the 24 countries whose NP/NS for RD is active, expired, approved but not active, under renewal or under development, and refer to each item of the survey related to the four EJP RD Pillars.

**Pillar 1- “National and International investments on research in the field of RD”**

**Does the NP/NS for RD of your country promote national calls for research projects?**

**Yes, 14 countries (58%):** Canada, Cyprus, Czech Republic, France, Georgia, Germany, Lithuania, Luxembourg, Norway, Portugal, Romania, Slovakia, Slovenia, Spain

**No, 9 countries (38%):** Austria, Bulgaria, Denmark, Estonia, Italy, Poland, Serbia, Switzerland, The Netherlands

**I don't know, 1 country (4%):** Malta

**Does the NP/NS for RD of your country promote transnational calls for research projects?**

**Yes, 11 countries (46%):** Canada, Cyprus, Czech Republic, Germany, Lithuania, Luxembourg, Norway, Portugal, Romania, Slovakia, Spain

**No, 11 countries (46%):** Austria, Bulgaria, Denmark, Estonia, Georgia, Italy, Poland, Serbia, Slovenia, Switzerland, The Netherlands

**I don't know, 2 countries (8%):** France, Malta

Eleven countries (46%) declare that their NP/NS for RD promotes both national and transnational calls for research projects (Canada, Cyprus, Czech Republic, Germany, Lithuania, Luxembourg, Norway, Portugal, Romania, Slovakia, Spain), two countries (8%) only national calls (Georgia, Slovenia), and one country (4%) that it promotes national calls, but not to know about international calls (France). In nine coun-

<sup>19</sup> The percentages refer to the 24 countries declaring to have a NP/NS for RD active, expired, under development or under approval. For the answers regarding the alignment status of the NP/NS for RD of the five countries answering that their NP/NS for RD or the list of measures are under renewal (respectively Cyprus, France, Portugal, Serbia, and Lithuania) it cannot be established if the answers refer to the last expired NP/NS for RD/expired list of measures, or to the new versions that are under development. Also, for Italy, it cannot be defined whether the answers refer to the expired NP/NS for RD, or to the new developed edition that is in the process of approval. When comparing the answers submitted in the three editions of the survey, only slight differences can be observed for France, Italy and Portugal, while more variation can be observed for Lithuania. The surveys have been filled by the same reference person over the three editions. For Cyprus such comparison is not possible, as the country participated only to the last edition of the survey.



tries (38%) the NP/NS for RD does not promote neither national nor transnational calls for research projects (Austria, Bulgaria, Denmark, Estonia, Italy, Poland, Serbia, Switzerland, The Netherlands) and one country (4%) replies not to know at all (Malta).

**Does the NP/NS for RD of your country foresee investments to share knowledge?**

<b>Yes, 9 countries (38%):</b> Canada, Cyprus, Georgia, Lithuania, Luxembourg, Norway, Poland, Slovenia, Spain
<b>No, 13 countries (54%):</b> Austria, Bulgaria, Czech Republic, Denmark, Estonia, Germany, Italy, Portugal, Romania, Serbia, Slovakia, Switzerland, The Netherlands
<b>I don't know, 2 countries (8%):</b> France, Malta

With regard to the investment to share knowledge, the NP/NS for RD of 9 countries (38%) foresees such investments (Canada, Cyprus, Georgia, Lithuania, Luxembourg, Norway, Poland, Slovenia, Spain), while in 13 countries (54%) the investments are not foreseen (Austria, Bulgaria, Czech Republic, Denmark, Estonia, Germany, Italy, Portugal, Romania, Serbia, Slovakia, Switzerland, The Netherlands), and two countries (8%) answer not to know (France, Malta).

Globally six countries (25%) show a positive alignment in all the areas of Pillar 1 (Canada, Cyprus, Lithuania, Luxembourg, Norway, Spain), while the remaining 18 countries (75%) answer no or not to know in one or more items pertaining to the activities of Pillar 1.

**Pillar 2- “Resources and services to foster research on RD”**

**Does the NP/NS for RD of your country support data repositories and tools for research on RD?**

<b>Yes, the NP/NS for RD promotes the development of data repositories and tools for RD research, 7 countries (30%):</b> Bulgaria, Estonia, Georgia, Malta, Romania, Slovakia, Slovenia
<b>Yes, the NP/NS for RD promotes the implementation of data repositories and tools for RD research: -</b>
<b>Yes, the NP/NS for RD promotes both the development and the implementation of data repositories and tools for RD research, 8 countries (33%):</b> Canada, France, Germany, Italy, Lithuania, Poland, Spain, Switzerland
<b>No, 8 countries (33%):</b> Austria, Cyprus, Denmark, Luxembourg, Norway, Portugal, Serbia, The Netherlands
<b>I don't know, 1 country (4%):</b> Czech Republic

Fifteen countries (63%) reference that their NP/NS for RD promotes the development and/or implementation of data repositories and tools for research on RD (Bulgaria, Canada, Estonia, France, Georgia, Germany, Italy, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, Spain, Switzerland). Of these fifteen, seven countries (47%) affirm that it promotes the development (Bulgaria, Estonia, Georgia, Malta, Romania, Slovakia, Slovenia), and eight countries (53%), both the development and implementation (Canada, France, Germany, Italy, Lithuania, Poland, Spain, Switzerland).

The development and/or implementation of data repositories and tools for research on RD are not supported by eight (33%) of the NP/NS for RD (Austria, Cyprus, Den-

mark, Luxembourg, Norway, Portugal, Serbia, The Netherlands), and one country (4%) answers not to know (Czech Republic).

The topic that is endorsed by 50% or more of the countries replying that their NP/NS for RD supports data repositories and tools for research on RD is represented by "Registries catalogues", (Bulgaria, France, Georgia, Germany, Italy, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, Spain, Switzerland). The other investigated topics are endorsed by less than 50% of the countries replying that their NP/NS for RD supports data repositories and tools for research on RD. For the detailed percentage rates of the support given by the NP/NS for RD regarding each investigated area of data repositories and tools for research on RD see Table 4.

**Table 4. Topics covered by the data repositories and tools for RD research that are supported by the NP/NS for RD, and countries covering them<sup>20</sup>**

<b>Registries catalogue, 13 countries (87%):</b> Bulgaria, France, Georgia, Germany, Italy, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, Spain, Switzerland
<b>Biobanks catalogue, 7 countries (47%):</b> Canada, Georgia, Italy, Lithuania, Malta, Slovenia, Spain
<b>Ontologies and codification, 7 countries (47%):</b> France, Georgia, Germany, Italy, Lithuania, Poland, Slovenia
<b>OMIC services, 2 countries (13%):</b> Canada, Lithuania
<b>Cell lines, 2 countries (13%):</b> Canada, Spain
<b>Animal models, 1 country (7%):</b> Canada
<b>Semantic Standards, 1 country (7%):</b> Poland
<b>Support for clinical/translational research, 7 countries (47%):</b> Canada, France, Georgia, Lithuania, Malta, Romania, Slovenia
<b>Access &amp; privacy control, 2 countries (13%):</b> Canada, Lithuania
<b>Data deposition &amp; analysis, 7 countries (47%):</b> Canada, Estonia, France, Germany, Italy, Lithuania, Poland
<b>Tools, 4 countries (27%):</b> Canada, Georgia, Lithuania, Spain
<b>Other: -</b>

**Does the NP/NS for RD of your country support FAIR\* data? (Findable, Accessible, Interoperable, Reusable)**

<b>Yes, 9 countries (38%):</b> Canada, France, Germany, Italy, Lithuania, Poland, Romania, Slovakia, Slovenia
<b>No, 12 countries (50%):</b> Austria, Bulgaria, Cyprus, Denmark, Estonia, Georgia, Luxembourg, Norway, Portugal, Serbia, Switzerland, The Netherlands
<b>I don't know, 3 countries (12%):</b> Czech Republic, Malta, Spain

The support to FAIR data is enforced by the NP/NS for RD of nine countries (38%, Canada, France, Germany, Italy, Lithuania, Poland, Romania, Slovakia, Slovenia), while twelve countries (50%) affirm that FAIR data are not supported by the NP/NS for RD (Austria, Bulgaria, Cyprus, Denmark, Estonia, Georgia, Luxembourg, Norway, Portugal, Serbia, Switzerland, The Netherlands), and three countries (12%) do not know (Czech Republic, Malta, Spain).

<sup>20</sup> Percentages referring to the 15 countries declaring that the NP/NS for RD supports the development or both the development and implementation of data repositories and tools for research on RD

**Does the NP/NS for RD promote the adoption of multidisciplinary/holistic approaches for RD?**

<b>Yes, 20 countries (84%):</b> Austria, Bulgaria, Canada, Cyprus, Denmark, Estonia, France, Georgia, Germany, Italy, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Switzerland
<b>No, 3 countries (12%):</b> Czech Republic, Norway, The Netherlands
<b>I don't know, 1 country (4%):</b> Malta

Finally, the adoption of multidisciplinary holistic approaches is promoted by the NP/NS for RD of twenty countries (84%, Austria, Bulgaria, Canada, Cyprus, Denmark, Estonia, France, Georgia, Germany, Italy, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Switzerland), not promoted by the NP/NS for RD of three countries (12%, Czech Republic, Norway, The Netherlands), while one country (4%) replies not to know (Malta).

Overall, when considering the activities of Pillar 2, nine countries (38%) reply in the affirmative to all items (Canada, France, Germany, Italy, Lithuania, Poland, Romania, Slovakia, Slovenia), while the other fifteen countries reply "No", or "I don't know" to one or more questions.

**Pillar 3- "Capacity building and empowerment"**

**Does the NP/NS for RD of your country promote training activities for RD?**

<b>Yes, 20 countries (84%):</b> Austria, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, France, Georgia, Germany, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain
<b>No, 3 countries (12%):</b> Norway, Switzerland, The Netherlands
<b>I don't know, 1 country (4%):</b> Italy

Regarding Pillar 3, twenty countries (84%) declare that the NP/NS for RD supports training activities for RD (Austria, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, France, Georgia, Germany, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain), three countries (12%) that the support is not in place (Norway, Switzerland, The Netherlands) and one country (4%) not to know (Italy).

The training activities supported by more than 50% of the NP/NS for RD concern "Data management", "Standards and quality of genetics/genomics data in clinical practice and laboratories" and "Online education courses".

The other investigated topics are endorsed by less than 50% of the countries replying that their NP/NS for RD supports RD trainings. For the detailed percentage rates of the support given by the NP/NS for RD regarding each investigated area of RD trainings see Table 5.

**Table 5. Topics covered by the training activities that are supported by the NP/NS for RD and countries covering them<sup>21</sup>**

<b>Data management, 5 countries (25%):</b> Canada, Georgia, Lithuania, Malta, Poland
<b>Data quality, 5 countries (25%):</b> Canada, Czech Republic, Georgia, Malta, Poland
<b>FAIR data, 2 countries (10%):</b> Canada, Poland
<b>Standards and quality of genetics/genomics data in clinical practice and laboratories, 7 countries (35%):</b> Canada, Czech Republic, Denmark, Georgia, Lithuania, Poland, Portugal
<b>Registries, 9 countries (45%):</b> Bulgaria, France, Georgia, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia
<b>Biobanks, 3 countries (15%):</b> Georgia, Germany, Poland
<b>Empowerment of the patients, 14 countries (70%):</b> Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Georgia, Luxembourg, Poland, Portugal, Romania, Slovakia, Slovenia, Spain
<b>Online education courses, 9 countries (45%):</b> Bulgaria, Cyprus, Czech Republic, Denmark, Georgia, Poland, Portugal, Romania, Spain
<b>Other, 4 countries (20%):</b> Austria, Estonia, Germany, Serbia

#### **Pillar 4- “Accelerated translation of research projects and improvement of outcomes of clinical studies”**

##### **Does the NP/NS for RD of your country promote a rapid translation of research results in clinical studies and healthcare?**

<b>Yes, 9 countries (38%):</b> Canada, France, Georgia, Germany, Italy, Lithuania, Romania, Slovenia, Spain
<b>No, 14 countries (58%):</b> Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Luxembourg, Norway, Poland, Portugal, Serbia, Slovakia, Switzerland, The Netherlands
<b>I don't know, 1 country (4%):</b> Malta

##### **Does the NP/NS for RD of your Country promote the development of innovative methodologies tailored for clinical trials?**

<b>Yes, 3 countries (12%):</b> Canada, Romania, Slovenia
<b>No, 17 countries (71%):</b> Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Georgia, Germany, Italy, Lithuania, Luxembourg, Norway, Portugal, Serbia, Slovakia, Switzerland, The Netherlands
<b>I don't know, 4 countries (17%):</b> France, Malta, Poland, Spain

Nine countries (38%) report that that their NP/NS for RD promotes the rapid translation of research results in clinical practice and healthcare (Canada, France, Georgia, Germany, Italy, Lithuania, Romania, Slovenia, Spain), and three of these that the promotion is enforced also towards the development of innovative methodologies tailored for clinical trials (12%, Canada, Romania, Slovenia). These three countries are the only answering that the NP/NS for RD promotes the development of innovative

<sup>21</sup> Percentages referring to the 20 countries declaring that the NP/NS for RD supports training activities for RD

methodologies tailored for clinical trials. One country (4%) answers not to know about the rapid translation of research results in clinical practice and healthcare (Malta) while for the promotion of the support to the development of innovative methodologies tailored for clinical trials four countries (17%) answer not to know (France, Malta, Poland, Spain). Finally, fourteen countries (58%) inform on not promoting the rapid translation of research results in clinical practice and healthcare (Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Luxembourg, Norway, Poland, Portugal, Serbia, Slovakia, Switzerland, The Netherlands), and seventeen countries (71%) when considering the development of innovative methodologies tailored for clinical trials (Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Georgia, Germany, Italy, Lithuania, Luxembourg, Norway, Portugal, Serbia, Slovakia, Switzerland, The Netherlands).

Overall, thirteen countries (54%) do not promote neither the promotion of the rapid translation of research results in clinical practice and healthcare, nor the development of innovative methodologies tailored for clinical trials (Austria, Bulgaria, Czech Republic, Denmark, Estonia, Luxembourg, Norway, Portugal, Serbia, Slovakia, Switzerland, The Netherlands).

#### Alignment status of other relevant RD activities than the NP/NS for RD with the activities promoted by the 4 EJP RD Pillars<sup>22</sup>

The assessment of the alignment status with the four EJP RD Pillars has also been made for other relevant RD activities, than the NP/NS for RD.

#### **Pillar 1 - “National and International investments on research in the field of RD”**

##### **Are there other public funding initiatives that promote national calls for research/networking in the field of RD in your country, apart from the NP/NS for RD?**

**Yes, 6 countries (24%):** Canada, Cyprus, Romania, Slovenia, Switzerland, Spain, The Netherlands

**No, 11 countries (44%):** Bulgaria, Czech Republic, Estonia, Georgia, Germany, Italy, Lithuania, Luxembourg, Portugal, Serbia, Slovakia

**I don't know, 8 countries (32%):** Austria, Denmark, France, Israel, Malta, Norway, Poland, Spain

##### **Are there private funding initiatives for national calls for research/networking in the field of RD in your country?**

**Yes, 5 countries (20%):** Bulgaria, Canada, Germany, Italy, The Netherlands

**No, 8 countries (32%):** Czech Republic, Estonia, Georgia, Lithuania, Serbia, Slovakia, Slovenia, Switzerland

**I don't know, 12 countries (48%):** Austria, Cyprus, Denmark, France, Israel, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Spain

Six countries (24%) refer to have other public funding initiatives than the NP/NS for RD that promote national calls for research/networking in RD (Canada, Cyprus, Romania, Slovenia, Switzerland, The Netherlands, Spain), and five countries (20%) that such

<sup>22</sup> Percentages referring to all 25 countries participating in the 2023 edition of the survey

activities are promoted by private funding initiatives (Bulgaria, Czech Republic, Estonia, Georgia, Germany, Italy, Lithuania, Luxembourg, Portugal, Serbia, Slovakia). Among these countries two (4%) show to have both other public and private funding initiatives that promote national calls for research projects (Canada, the Netherlands).

On the other hand, eleven countries (44%) answer not to have other public funding initiatives than the NP/NS for RD that promote national calls for research/networking in RD (Bulgaria, Czech Republic, Estonia, Georgia, Germany, Italy, Lithuania, Luxembourg, Portugal, Serbia, Slovakia), and eight countries (32%) declare not to know (Austria, Denmark, France, Israel, Malta, Norway, Poland, Spain). When referring to the private funding initiatives that promote national calls for research/networking in RD, eight countries (11%) report the lack of these (Czech Republic, Estonia, Georgia, Lithuania, Serbia, Slovakia, Slovenia, Switzerland), and 12 countries (48%) not to know (Austria, Cyprus, Denmark, France, Israel, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Spain).

It can be therefore observed that 5 countries (20%) do not have other public nor private funding initiatives that promote national calls for research/networking in RD (Estonia, Georgia, Lithuania, Serbia, The Netherlands).

**Are there other public funding initiatives that promote transnational calls for research/networking in the field of RD in your country, apart from the NP/NS for RD?**

**Yes, 3 countries (12%):** Canada, Spain, The Netherlands

**No, 12 countries (48%):** Bulgaria, Czech Republic, Estonia, Georgia, Germany, Lithuania, Italy, Portugal, Serbia, Slovakia, Slovenia, Switzerland

**I don't know, 10 countries (40%):** Austria, Cyprus, Denmark, France, Israel, Luxembourg, Malta, Norway, Poland, Romania

**Are there private funding initiatives for transnational calls for research/networking in the field of RD in your country?**

**Yes, 3 countries (12%):** Bulgaria, Italy, Spain

**No, 10 countries (40%):** Estonia, Czech Republic, Georgia, Germany, Lithuania, Serbia, Slovakia, Slovenia, Switzerland, The Netherlands

**I don't know, 12 countries (48%):** Austria, Canada, Cyprus, Denmark, France, Israel, Luxembourg, Malta, Norway, Poland, Portugal, Romania

Moving to other relevant RD funding initiatives that promote calls for research/networking in RD at transnational level, three countries (12%) inform about the presence of such public initiatives (Canada, Spain, The Netherlands), and three countries (12%) of such private initiatives (Bulgaria, Italy, Spain). Twelve countries (48%) answer that there are no other public funding initiatives that promote calls for research/networking in RD at transnational level (Bulgaria, Czech Republic, Estonia, Georgia, Germany, Lithuania, Italy, Portugal, Serbia, Slovakia, Slovenia, Switzerland), and 10 countries (40%) when considering the promotion of these initiatives at private level (Estonia, Czech Republic, Georgia, Germany, Lithuania, Serbia, Slovakia, Slovenia, Switzerland, The Netherlands). 10 countries (40%) do not know about the existence of other public funding initiatives that promote calls for research/networking in RD at transnational level (Austria, Cyprus, Denmark, France, Israel, Luxembourg, Malta, Norway, Poland, Romania), and 12 countries (48%) about the existence of other private funding initiatives that promote calls for research/networking in RD at trans-

national level (Austria Canada, Cyprus, Denmark, France, Israel, Luxembourg, Malta, Norway, Poland, Portugal, Romania).

From these results it appears that only in one country (4%) both other public and private funding initiatives than the NP/NS for RD that promote calls for research/networking in RD at transnational level exist (Spain), whereas in 9 countries (36%) there emerges lack of promotion of these transnational funding initiatives at public and private level (Czech Republic, Estonia, Georgia, Germany, Lithuania, Serbia, Slovakia, Slovenia, Switzerland).

**Are investments to share knowledge foreseen by other public national initiatives than the NP/NS for RDs?**

<b>Yes, 4 countries (16%):</b> Italy, Luxembourg, Serbia, The Netherlands
<b>No, 10 countries (40%):</b> Bulgaria, Czech Republic, Estonia, Georgia, Germany, Lithuania, Portugal, Slovakia, Slovenia, Switzerland
<b>I don't know, 11 countries (44%):</b> Austria, Canada, Cyprus, Denmark, France, Israel, Malta, Norway, Poland, Romania, Spain

**Are investments to share knowledge foreseen by private national initiatives for RD?**

<b>Yes, 3 countries (12%):</b> Bulgaria, Cyprus, Italy
<b>No, 10 countries (40%):</b> Czech Republic, Estonia, Georgia, Lithuania, Luxembourg, Serbia, Slovakia, Slovenia, Switzerland, The Netherlands
<b>I don't know, 12 countries (48%):</b> Austria, Canada, Denmark, France, Israel, Germany, Malta, Norway, Poland Portugal, Romania, Spain

Investments to share knowledge at national level are foreseen in 4 countries (16%) by other public initiatives than the NP/NS for RD (Italy, Luxembourg, Serbia, The Netherlands), and in three countries (12%) by private national initiatives (Bulgaria, Cyprus, Italy), with only one country (4%) is foreseeing both public and private initiatives (Italy).

The absence of investments to share knowledge by other public national initiatives than the NP/NS for RD, is reported by 10 countries (40%, Bulgaria, Czech Republic, Estonia, Georgia, Germany, Lithuania, Portugal, Slovakia, Slovenia, Switzerland), and by 10 countries (40%) when looking at private national initiatives (Czech Republic, Estonia, Georgia, Lithuania, Luxembourg, Serbia, Slovakia, Slovenia, Switzerland, The Netherlands).

The countries not knowing about the existence of such public initiatives are 11 (44%, Austria, Canada, Cyprus, Denmark, France, Israel, Malta, Norway, Poland, Romania, Spain). The amount raises to 12 (48%) when considering such private initiatives (Austria, Canada, Denmark, France, Israel, Germany, Malta, Norway, Poland Portugal, Romania, Spain).

In all it appears that one country (4%) shows alignment of other relevant RD initiatives than the NP/NS for RD on all areas investigated for Pillar 1 at public level (The Netherlands).

**Pillar 2- “Resources and services to foster research on RD”**

**Is there an advisory body of national experts for Research and Innovation in your country?<sup>23</sup>**

<b>Yes, an advisory body exists, specific for RD, 1 country (7%):</b> Romania
<b>Yes, and advisory exists, but not specific for RD, 10 countries (72%):</b> Bulgaria, Canada, Estonia, Germany, Luxembourg, Portugal, Serbia, Slovenia, Spain, The Netherlands
<b>No, 1 country (7%):</b> Switzerland
<b>I don't know, 2 countries (14%):</b> Cyprus, Italy

The information on the presence of an advisory body of national experts for research and innovation is available only for fourteen countries (Bulgaria, Canada, Cyprus, Estonia, Germany, Italy, Luxembourg, Portugal, Romania, Serbia, Slovenia, Spain, Switzerland, The Netherlands). Of these fourteen, one country (7%) replies that it is provided by an advisory body specific for RD (Romania), ten countries (72%) that the advisory body is not specific for RD (Bulgaria, Canada, Estonia, Germany, Luxembourg, Portugal, Serbia, Slovenia, Spain, The Netherlands), one country (7%) not to be provided by an advisory body of national experts for research and innovation (Switzerland), and two countries (14%) that they do not know (Cyprus, Italy).

**Are there other public initiatives, than the NP/NS for RD of your country, that support data repositories and tools for research on RD?**

<b>Yes, other public initiatives promote the development of data repositories and tools for RD research (8%), 2 countries:</b> Bulgaria, Serbia
<b>Yes, other public initiatives promote the implementation of data repositories and tools for RD research: -</b>
<b>Yes, other public initiatives promote both the development and the implementation of data repositories and tools for RD research, 4 countries (16%):</b> Canada, Spain, Switzerland, The Netherlands
<b>No, 10 countries (40%):</b> Czech Republic, Estonia, Georgia, Germany, Italy, Lithuania, Luxembourg, Portugal, Slovakia, Slovenia
<b>I don't know, 9 countries (36%):</b> Austria, Cyprus, Denmark, France, Israel, Malta, Norway, Poland, Romania

In six countries (24%) there are other public funding initiatives than the NP/NS for RD that support data repositories and tools for research on RD. Among these, in two countries (8%) the initiatives promote the development of data repositories and tools (Bulgaria, Serbia), and in four countries (16%) both the development and implementation (Canada, Spain, Switzerland, The Netherlands). Ten countries (40%) reply that there are no other public funding initiatives than the NP/NS for RD that support data repositories and tools for research on RD (Czech Republic, Estonia, Georgia, Germany, Italy, Lithuania, Luxembourg, Portugal, Slovakia, Slovenia), and nine countries (36%) not to know (Austria, Cyprus, Denmark, France, Israel, Malta, Norway, Poland, Romania).

The topics endorsed by 50% or more of the countries replying to have other relevant RD public initiatives than the NP/NS for RD that support data repositories and tools for research on RD are represented by "Registries catalogues", (Bulgaria, Spain, Switzer-

<sup>23</sup> No information available for Austria, Czech Republic, Denmark, France, Georgia, Israel, Lithuania, Malta, Norway, Poland, Slovakia



land) and “OMIC services” (Canada, Spain, The Netherlands). The other investigated topics are endorsed by less than 50% of the countries replying that other public funding initiatives than the NP/NS for RD support data repositories and tools for research on RD. For the detailed percentage rates of the support given by the other public funding initiatives regarding each investigated area of data repositories and tools for research on RD see Table 6.

**Table 6. Topics covered by the public initiatives other than the NP/NS for RD that support data repositories and tools for RD research and countries covering them** <sup>24</sup>

<b>Registries catalogue, 3 countries (50%):</b> Bulgaria, Spain, Switzerland
<b>Biobanks catalogue, 2 countries (33%):</b> Spain, The Netherlands
<b>Ontologies and codification:</b> -
<b>OMIC services, 3 countries (50%):</b> Canada, Spain, The Netherlands
<b>Cell lines, 2 countries (33%):</b> Spain, The Netherlands
<b>Animal models, 2 countries (33%):</b> Spain, The Netherlands
<b>Semantic standards:</b> -
<b>Support for clinical/translational research, 1 country (17%):</b> The Netherlands
<b>Access &amp; privacy control, 2 countries (33%):</b> Canada, The Netherlands
<b>Data deposition and analysis, 2 countries (33%):</b> Canada, The Netherlands
<b>Tools, 2 countries (33%):</b> Canada, The Netherlands
<b>Other, 1 country (17%):</b> Serbia

**Are there other private initiatives of your country, that support data repositories and tools for research on RD?**

<b>Yes, other private initiatives promote the development of data repositories and tools for RD research (4%), 1 country:</b> Germany
<b>Yes, other private initiatives promote the implementation of data repositories and tools for RD research:</b> -
<b>Yes, other private initiatives promote both the development and the implementation of data repositories and tools for RD research, 4 countries (16%):</b> Bulgaria, Italy, Spain, The Netherlands
<b>No, 8 countries (32%):</b> Czech Republic, Georgia, Lithuania, Luxembourg, Serbia, Slovakia, Slovenia, Switzerland
<b>I don't know, 12 countries (48%):</b> Austria, Canada, Cyprus, Denmark, Estonia, France, Israel, Malta, Norway, Poland Portugal, Romania

Private funding initiatives that support data repositories and tools for research on RD are reported by five countries (20%, Germany, Bulgaria, Italy, Spain, The Netherlands), with one country (4%) having private funding initiatives that support the development of data repositories and tool for research on RD (Germany), and four countries (16%) having private funding initiatives that support both the development and the implementation of data repositories and tools for research on RD (Bulgaria, Italy, Spain, The Netherlands). Eight countries (32%) report the absence of similar private initiatives (Czech Republic, Georgia, Lithuania, Luxembourg, Serbia, Slovakia, Slovenia, Switzerland), and twelve countries (48%) do not know.

<sup>24</sup> Percentages referring to the 6 countries declaring that other public RD activities than the NP/NS for RD that support data repositories and tools for research on RD

The topics endorsed by 50% or more of the countries replying to have relevant RD private initiatives that support data repositories and tools for research on RD are represented by “Registries catalogues”, (Bulgaria, Italy, Spain, The Netherlands), “Biobanks catalogue”, (Italy, Spain, The Netherlands), “OMIC services” (Canada, Spain, The Netherlands), “Data deposition and analysis” (Germany, Spain, The Netherlands), and “Tools” (Italy, Spain, The Netherlands). The other investigated topics are endorsed by less than 50% of the countries replying to have private funding initiatives that support data repositories and tools for research on RD. For the detailed percentage rates of the support given by the private funding initiatives regarding each investigated area of data repositories and tools for research on RD see Table 7.

**Table 7. Topics covered by the private initiatives that support data depositories and tools for RD research and countries covering them <sup>25</sup>**

<b>Registries catalogue, 4 countries (80%):</b> Bulgaria, Italy, Spain, The Netherlands
<b>Biobanks catalogue, 3 countries (60%):</b> Italy, Spain, The Netherlands
<b>Ontologies and codification, 1 country (20%):</b> Italy
<b>OMIC services:</b> -
<b>Cell lines, 2 countries (40%):</b> Spain, The Netherlands
<b>Animal models, 2 countries (40%):</b> Spain, The Netherlands
<b>Semantic standards, 1 country (20%):</b> Italy
<b>Support for clinical/translational research, 1 country (20%):</b> The Netherlands
<b>Access &amp; privacy control, 1 country (20%):</b> The Netherlands
<b>Data deposition and analysis, 3 countries (60%):</b> Germany, Spain, The Netherlands
<b>Tools, 3 countries (60):</b> Italy, Spain, The Netherlands
<b>Other:</b> -

**Are there other national initiatives for RD, than the NP/NS, that support FAIR\* data? (\*Findable, Accessible, Interoperable, Reusable)**

<b>Yes, 6 countries (24%):</b> Italy, Portugal, Romania, Slovenia, Switzerland, The Netherlands
<b>No, 8 countries (32%):</b> Bulgaria, Czech Republic, Georgia, Lithuania, Luxembourg, Serbia, Slovakia, Spain
<b>I don't know, 11 countries (44%):</b> Austria, Canada, Cyprus, Denmark, Estonia, France, Germany, Israel, Malta, Norway, Poland

Six countries (24%) have other initiatives than the NP/NS for RD that support FAIR data (Italy, Portugal, Romania, Slovenia, Switzerland, The Netherlands), while no other initiatives for the support to FAIR data are available in eight countries (32%, Bulgaria, Czech Republic, Georgia, Lithuania, Luxembourg, Serbia, Slovakia, Spain). The remaining eleven countries (44%) reply not to know (Austria, Canada, Cyprus, Denmark, Estonia, France, Germany, Israel, Malta, Norway, Poland).

When asked for specifications, the six countries refer that the support to FAIR data given by other relevant RD activities than the NP/NS for RD ranges from the promotion of training activities to the use of FAIR data by scientific societies and intergovernmental organisations such as Elixir, or the Go-Fair foundation.

<sup>25</sup> Percentages referring to the 5 countries declaring that other private RD activities than the NP/NS for RD support data repositories and tools for research on RD

**Are there other national initiatives, than the NP/NS for RD, that promote the adoption of multidisciplinary approaches for RD?**

**Yes, 6 countries (24%):** Bulgaria, Canada, Italy, Romania, Slovenia, The Netherlands

**No, 8 countries (32%):** Czech Republic, Estonia, Georgia, Lithuania, Luxembourg, Portugal, Slovakia, Switzerland

**I don't know, 11 countries (44%):** Austria, Cyprus, Denmark, France, Germany, Israel, Malta, Norway, Poland, Serbia, Spain

The last item investigating the presence of other relevant RD activities than the NP/NS for RD that fall under the objectives of Pillar 2 shows that six countries (24%) have national initiatives that promote the adoption of multidisciplinary holistic approaches for RD (Bulgaria, Canada, Italy, Romania, Slovenia, The Netherlands), and that, whereas eight countries (32%) do not have these type of other initiatives (Czech Republic, Estonia, Georgia, Lithuania, Luxembourg, Portugal, Slovakia, Switzerland). Finally, respondents from eleven countries (44%) do not know on this item (Austria, Cyprus, Denmark, France, Germany, Israel, Malta, Norway, Poland, Serbia, Spain).

Given the high variety of characteristics investigated by the survey in relation to the other initiatives than the NP/NS for RD when considering the activities of Pillar 2, a summary of the countries reporting initiatives for all items has not been performed, since the results are too scattered.

**Pillar 3- "Capacity building and empowerment"**

**Are there other initiatives, than the NP/NS for RD, that support training activities for RD?**

**Yes, 6 countries (24%):** Bulgaria, Italy, Portugal, Romania, Serbia, The Netherlands

**No, 8 countries (32%):** Czech Republic, Estonia, Georgia, Lithuania, Luxembourg, Slovakia, Slovenia, Switzerland

**I don't know, 11 countries (44%):** Austria, Canada, Cyprus, Denmark, France, Germany, Israel, Malta, Norway, Poland, Spain

Other initiatives than the NP/NS for RD that support RD trainings can be found in 6 countries (24%, Bulgaria, Italy, Portugal, Romania, Serbia, The Netherlands), while 8 countries (32%) do not report other RD initiatives dedicated to trainings (Czech Republic, Estonia, Georgia, Lithuania, Luxembourg, Slovakia, Slovenia, Switzerland), and 11% answer not to know (Austria, Canada, Cyprus, Denmark, France, Germany, Israel, Malta, Norway, Poland, Spain).

The topics of the RD trainings supported by 50% or more of the countries reporting of other initiatives than the NP/NS for RD are represented by: "Online education courses", (Bulgaria, Italy, Portugal, Romania, Serbia), "Empowerment of the patients", (Bulgaria, Italy, Romania, The Netherlands), "Standards and quality of genetics/genomics data in clinical practice and laboratories", (Italy, Romania, Serbia, The Netherlands), and "Data management" (Italy, Romania, The Netherlands). The other investigated topics are endorsed by less than 50% of the countries, where RD trainings are supported by other initiatives than the NP/NS for RD. For the detailed percentage rates of the support given by other initiatives than the NP/NS for RD regarding each investigated area of RD trainings see Table 8.

**Table 8. Topics covered by the training activities that are supported by the NP/NS for RD and countries covering them <sup>26</sup>**

<b>Data management, 3 countries (50%):</b> Italy, Romania, The Netherlands
<b>Data quality, 2 countries (33%):</b> Italy, Romania
<b>FAIR data, 1 country (17%):</b> Italy
<b>Standards and quality of genetics/genomics data in clinical practice and laboratories, 4 countries (67%):</b> Italy, Romania, Serbia, The Netherlands
<b>Registries, 2 countries (33%):</b> Italy, Romania
<b>Biobanks, 1 country (17%):</b> Italy
<b>Empowerment of the patients, 4 countries (67%):</b> Bulgaria, Italy, Romania, The Netherlands
<b>Online education courses, 5 countries (83%):</b> Bulgaria, Italy, Portugal, Romania, Serbia
<b>Other: -</b>

**Pillar 4- “Accelerated translation of research projects and improvement of outcomes of clinical studies”**

**Are there other initiatives, than the NP/NS for RD, that promote a rapid translation of research results in clinical studies and healthcare?**

<b>Yes, 3 countries (12%):</b> Italy, Serbia, The Netherlands
<b>No, 8 countries (32%):</b> Bulgaria, Czech Republic, Georgia, Lithuania, Luxembourg, Portugal, Slovakia, Slovenia
<b>I don't know, 14 countries (56%):</b> Austria, Canada, Cyprus, Denmark, Estonia, France, Germany, Israel, Malta, Norway, Poland, Romania, Spain, Switzerland

**Are there other initiatives, than the NP/NS for RD, that promote the development of innovative methodologies tailored for clinical trials?**

<b>Yes, 1 country (4%):</b> Spain
<b>No, 11 countries (44%):</b> Bulgaria, Czech Republic, Estonia, Georgia, Lithuania, Luxembourg, Portugal, Serbia, Slovakia, Slovenia, The Netherlands
<b>I don't know, 13 countries (52%):</b> Austria, Canada, Cyprus, Denmark, France, Germany, Israel, Italy, Malta, Norway, Poland, Romania, Switzerland

Considering the activities of Pillar 4, three countries (12%) reply to have other initiatives than the NP/NS for RD that promote a rapid translation of research results in clinical studies and healthcare (Italy, Serbia, The Netherlands), while another country (4%) is the only who refers of other initiatives that promote the development of innovative methodologies tailored for clinical trials (Spain).

The absence of other initiatives than the NP/NS for RD that promote a rapid translation of research results in clinical studies and healthcare is reported by eight countries (32%, Bulgaria, Czech Republic, Georgia, Lithuania, Luxembourg, Portugal, Slovakia, Slovenia), and fourteen countries (56%) answer not to know (Austria, Canada, Cyprus, Denmark, Estonia, France, Germany, Israel, Malta, Norway, Poland, Romania,

<sup>26</sup> Percentages referring to the 6 countries declaring that other RD activities than the NP/NS for RD supports RD trainings

Spain, Switzerland). Eleven countries (44%) inform on the lack of other initiatives that promote the development of innovative methodologies tailored for clinical trials (Austria, Canada, Cyprus, Denmark, France, Germany, Israel, Italy, Malta, Norway, Poland, Romania, Switzerland), and respondents from thirteen countries (52%) answer not to know if such activities exist (Austria, Canada, Cyprus, Denmark, France, Germany, Israel, Italy, Malta, Norway, Poland, Romania, Switzerland).

**Do you want to highlight any other aspect regarding the national policies and initiatives for RD of your country that were not included in the present survey?**

**Yes (20%):** Georgia, Luxembourg, Norway, Portugal

**No (80%):** Czech Republic, Denmark, Estonia, France, Germany, Israel, Italy, Lithuania, Malta, Poland, Romania, Serbia, Slovakia, Slovenia, Spain, Switzerland, The Netherlands

One further question left a free text space to highlight any other aspect of national RD policies and initiatives not included in the survey.

Five countries (20%) furnish other information (Austria, Georgia, Luxembourg, Norway, Portugal). The topics highlighted by the five countries have been:

- the interdependence between transnational activities and funding, given the limited resources of national activities
- the complexity of finding money and commitment for registries beyond international initiatives
- the presence of health literacy and self-empowerment trainings for RD patients, in line with EU recommendations, enforced by a national RD patient association, and delivered as webinars, face to face workshops, and online workshops, in collaboration with the national hub of European Patients' Academy on Therapeutic Innovation (EUPATI)
- the fact that the NP/NS for RD does not go in depth in research
- the postponement of the validation of the NS for RD due to the renovation of the Ministry of Health, and the investments of the country in laboratory research to facilitate diagnosis and treatment, as well as in RD patients centred initiatives facing integration, labour and education issues.

[Impact of the EJP RD activities at national level<sup>27</sup>](#)

In addition to the items assessing the alignment process of the NP/NS for RD and of other relevant RD initiatives with the four EJP RD Pillars, the 2023 edition investigated the perceived impacts that the EJP RD has had on national RD activities.

**Did the EJP RD activities promote, trigger, or help to enforce RD undertakings that were not implemented or deemed so far in your country?**

**Yes, 16 countries (64%):** Austria, Canada, Cyprus, Czech Republic, Georgia, Germany, Israel, Italy, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Spain, The Netherlands

**No, 9 countries (36%):** Bulgaria, Denmark, Estonia, France, Luxembourg, Norway, Serbia, Slovenia, Switzerland

<sup>27</sup> Data referring to all 25 countries that submitted the survey

The most important impacts of the EJP RD on RD national activities can be observed in the “Promotion, triggering or help in the enforcement of RD undertakings not implemented earlier in the countries”, with sixteen countries (64%) referring of positive impacts (Austria, Canada, Cyprus, Czech Republic, Georgia, Germany, Israel, Italy, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Spain, The Netherlands). The topics on which an impact has been reported, in descending order of frequency, are: “Increased participation in transnational calls for research projects”, “Increased participation in national calls for research projects”, “Support to the implementation of FAIR data”, “Promotion of rapid translation of research results into clinical studies and healthcare” and “Promotion of the development of innovative methodologies tailored for clinical trials”.

**Did the EJP RD activities promote, trigger, or help the establishment and/or implementation of data repositories and tools for research in RD?**

**Yes, 9 countries (36%):** Austria, Cyprus, Czech Republic, Georgia, Italy, Malta, Poland, Portugal, Slovakia

**No, 16 countries (64%):** Bulgaria, Canada, Denmark, Estonia, France, Germany, Israel, Lithuania, Luxembourg, Norway, Romania, Serbia, Slovenia, Spain, Switzerland, The Netherlands

The second area in terms of presence of impacts is the “Promotion, triggering or help to the establishment of RD training activities”, cited by twelve countries (48%, Austria, Bulgaria, Cyprus, France, Georgia, Italy, Lithuania, Malta, Poland, Portugal, Romania, Slovakia). The topics of the RD training activities on which the EJP RD had an impact, reported in descending order of frequency, are “Online education courses”, “Empowerment of the patients”, “Registries”, “Biobanks”, “Data management”, “Data quality” (the last three with the same percentage rate), “FAIR data”, “Standards and quality of genetics/genomics data in clinical practice and laboratories”.

**Did the EJP RD activities promote, trigger, or help the establishment of RD training activities?**

**Yes, 12 countries (48%):** Austria, Bulgaria, Cyprus, France, Georgia, Italy, Lithuania, Malta, Poland, Portugal, Romania, Slovakia

**No, 13 countries (52%):** Canada, Czech Republic, Denmark, Estonia, Germany, Israel, Luxembourg, Norway, Serbia, Slovenia, Spain, Switzerland, The Netherlands

Finally, the third area in terms of impacts is the “Promotion, triggering or help in the establishment and/or implementation of data repositories and tools for research in RD”, that has been indicated by nine countries (36%, Austria, Cyprus, Czech Republic, Georgia, Italy, Malta, Poland, Portugal, Slovakia). The topics for which there has been a positive impact are (in descending order of frequency): “Registries catalogue”, “Biobanks catalogue”, “Ontologies and codification”, “Support for clinical/translational research”, “Data deposition and analysis” (the last two with the same percentage rate), “Tools” and “Access & privacy control”, “Semantic standards” (the last two with the same percentage rate). Topics that were not enhanced are “OMIC services”, “Cell lines” and, “Animal models”.

Overall, eight countries (32%) refer that EJP RD has had an impact on all three areas (Austria, Cyprus, Georgia, Italy, Malta, Poland, Portugal, Slovakia), thirteen countries

(52%) on at least two areas (Austria, Cyprus, Czech Republic, Georgia, Italy, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Spain, The Netherlands), and eighteen countries (72%) on at least one area (Austria, Bulgaria, Canada, Cyprus, Czech Republic, France, Germany, Israel, Italy, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Spain, The Netherlands). Seven countries (28%) inform that EJP RD did not have impacts at national level on the investigated areas (Denmark, Estonia, Luxembourg, Norway, Serbia, Slovenia, Switzerland).

Below Tables 9 to 11 summarise the specifications for the three questions on the impact of the EJP RD activities.

**Table 9. Areas in which the EJP RD activities promoted, triggered, or helped to enforce RD undertakings that were not implemented or deemed so far in the countries<sup>28</sup>**

<b>Increased participation in national calls for research projects, 6 countries (38%):</b> Cyprus, Czech Republic, Georgia, Poland, Portugal, Romania
<b>Increased participation in transnational calls for research projects, 11 countries (69%):</b> Austria, Canada, Cyprus, Georgia, Germany, Israel, Lithuania, Portugal, Slovakia, Spain, The Netherlands
<b>Support to the implementation of FAIR data, 5 countries (31%):</b> Italy, Malta, Poland, Slovakia, The Netherlands
<b>Promotion of rapid translation of research results into clinical studies and healthcare, 3 countries (19%):</b> Georgia, Romania, Slovakia
<b>Promotion of the development of innovative methodologies tailored for clinical trials, 2 countries (13%):</b> Georgia, Romania
<b>No: -</b>

**Table 10 Areas in which the EJP RD activities promoted, triggered, or helped to the establishment and/or implementation of data repositories and tools for re-search in RD in the countries<sup>29</sup>**

<b>Registries catalogue, 8 countries (89%):</b> Austria, Cyprus, Czech Republic, Georgia, Italy, Malta, Poland, Slovakia
<b>Biobanks catalogue, 7 countries (78%):</b> Austria, Cyprus, Georgia, Italy, Malta, Poland, Slovakia
<b>Ontologies and codification, 6 countries (67%):</b> Austria, Georgia, Italy, Poland, Portugal, Slovakia
<b>OMIC services: -</b>
<b>Cell lines: -</b>
<b>Animal models: -</b>
<b>Semantic standards, 2 countries (22%):</b> Italy, Poland

<sup>28</sup> Percentages referring to the 15 countries answering that the EJP RD activities promoted, triggered, or helped to enforce RD undertakings that were not implemented or deemed so far in the country

<sup>29</sup> Percentages referring to the 9 countries answering that the EJP RD activities promoted, triggered, or helped the establishment and/or implementation of data repositories and tools for research in RD

<b>Support for clinical/translational research, 4 countries (44%):</b> Cyprus, Georgia, Portugal, Slovakia
<b>Access &amp; privacy control, 2 countries (22%):</b> Georgia, Slovakia
<b>Data deposition and analysis, 4 countries (44%):</b> Georgia, Italy, Poland, Slovakia
<b>Tools, 3 countries (33%):</b> Georgia, Italy, Poland
<b>Other:</b> -

**Table 11 Training areas in which the EJP RD activities promoted, triggered, or helped to the establishment of the training activities in the countries** <sup>30</sup>

<b>Data management, 5 countries (42%):</b> Italy, Malta, Poland, Romania, Slovakia
<b>Data quality, 5 countries (42%):</b> Italy, Lithuania, Malta, Poland, Romania
<b>FAIR data, 4 countries (33%):</b> Italy, Lithuania, Malta, Poland
<b>Standards and quality of genetics/genomics data in clinical practice and laboratories, 3 countries (25%):</b> Cyprus, Poland, Romania
<b>Registries, 7 countries (58%):</b> Cyprus, Georgia, Italy, Malta, Poland, Romania, Slovakia
<b>Biobanks, 5 countries (42%):</b> Cyprus, Georgia, Italy, Malta, Poland
<b>Empowerment of the patients, 8 countries (67%):</b> Bulgaria, Cyprus, Georgia, Lithuania, Poland, Portugal, Romania, Slovakia
<b>Online education courses, 10 countries (83%):</b> Austria, Bulgaria, Cyprus, France, Georgia, Italy, Lithuania, Poland, Romania, Slovakia
<b>Other:</b> -

The six countries participating for the first time to the survey (Cyprus, Denmark, Malta, Norway, Slovenia, Switzerland) have been furthermore asked for the reasons for not participating to the previous editions. The responses include the lack of involvement/awareness on the existence of this data collection, the absence of a NP/NS for RD or the recent involvement in the field, as well as the efforts to face the Covid-19 pandemic, as reported in Table 12.

**Table 12. Reasons given by the missing countries of the editions 2020/2021 of the survey for not participating formerly to the survey**<sup>31</sup>

Cyprus	I was not aware
Denmark	I have not been involved in this field before 2022, so I don't know
Malta	public health staff were completely tasked on Covid duties during 2020, 2021 and part of 2022 as well
Norway	Norway got its first strategy in 2021
Slovenia	/
Switzerland	We were not asked to participate

<sup>30</sup> Percentages referring to the 12 countries declaring that the EJP RD activities promoted, triggered, or helped the establishment of RD training activities

<sup>31</sup> Questions reserved to the 2023 participants that did not participate to the previous editions of the survey



The 25 responding countries have finally been asked to describe the most significant changes in the RD area occurred since 2019, starting year of the EJP RD. From an overview it emerges that seven of the nineteen European countries report activities related to the ERNs (Austria, Bulgaria, Czech Republic, Denmark, Estonia, Luxembourg, Slovakia, The Netherlands).

Other topics representing the most important changes of the countries in the RD area since 2019 have been: sharing of knowledge on RD; tools for RD; enhancement in diagnosis; broadening of newborn screening; enhancements at policy and legal level; increased access to orphan drugs; improvements related to patients organisations; creation of national centres for RD; Patient therapeutic education; implementation of measures of the plans and strategies; increase of funding dedicated to RD research; wider participation in RD transnational projects; social and psychological tools; hotlines; regulations on telemedicine; increased involvement of the NMGs; registries; genetic testing.

In Table 13 the detailed answers per country.

**Table 13. Most significant changes reported by the countries in the RD area since 2019**

Austria	Knowledge on RD and institutions/tools for RD (CoE, ERNs, Orphanet,...) have become known better than previously in the medical community, the ERNs have been in place longer and it is clearer what impact they have (or don't have)
Bulgaria	The growing interest in ERN
Canada	The most significant changes occurred in the RD area in Canada since 2019 is the capacity to share phenotypic and genotypic data internationally to diagnose rare diseases and to quickly identify models to study newly identified genes
Cyprus	Progress in new diagnostic tools
Czech Republic	The most significant change since 2019 has been the several fold: 1. Broadening of the nationwide newborn screening programme with SMA and SCID (since 2021) 2. Official de iure legal anchoring of Czech ERN teams into Health care legislature according to Art 113a of Act 372/2011 Coll and their listing in Bulletin 1/2022 of the Czech Ministry of Health – these centres received official status of Centres of highly specialised care 3. Legal anchoring of special access to orphan medicinal products and establishment of dedicated committees involving patients – amendment of Act 48/1997 Coll. 4. Legal anchoring and definition of a patient organisation into Art 113f of Act 372/2011 Coll. However, we were not able to push through the 3rd National Strategy for Rare Diseases due to bureaucratic obstacles.
Denmark	Crossnational collaboration and coordination and ERN's
Estonia	Creation of a national RD competence center at the Tartu University Hospital
France	The different measures implemented by the PNMR3, the Third Rare Disease National Plan. In particular for Patient Therapeutic Education
Georgia	The national budget for rare diseases has more than doubled
Germany	No significant changes, continuation of existing initiatives

Israel	No significant changes
Italy	The approval of the New National Plan for rare diseases (PNMR 2023-2025)
Lithuania	From the perspective of funding organization, the most significant change was the opening of funding opportunities for transnational research on RD. Participation in the calls was active resulting in 4 projects funded (1 per Call). In 2019 one of the gaps was funding for research. This was partially addressed by the Research Council participation in EJP RD. Consequently, the attention was drawn to RD community, to the topic, and this laid the foundation for strengthening of research competences, for policy engagement with the final benefit for Lithuanian patients.
Luxembourg	<ul style="list-style-type: none"> <li>- Development of the National ERN Coordination Hub (coordinated by the Centre Hospitalier de Luxembourg, CHL, and patient association ALAN)</li> <li>- Set-up of a national telephone hotline (RD Infoline)</li> <li>- Set-up of a national psycho-social coordination service for RD patients and their families</li> <li>- Realization of a RD census (first national RD inventory)</li> <li>- Publication and distribution of a guideline that facilitates access to information on administrative rights and procedures</li> </ul>
Malta	Initial phase of the automation of data
Norway	The strategy in 2021 has started many important processes in the field of rare diseases
Poland	Development and implementation of the National Plan for Rare Diseases: Polish Registry for RD and Information Platform RD, introduction of high-throughput techniques to molecular diagnostics, newborn screening toward 30 RDs drug programs in selected RDs
Portugal	Increased involvement of elements of the National Mirror Group of the EJPRD in activities related to the Investigation, like: Increased active participation of rare disease patient representatives Increased participation of the Foundation for Portuguese Science and Technology Involvement of the Portuguese Agency for Clinical Research and Biomedical Innovation. Supporting to increased participation in national calls for research projects and transnational calls for research projects.
Romania	Regulation of the legislative framework for the implementation of TELE-MEDICINE solutions including Rare Diseases. (GEO no. 196/ 18.XI.2020 completes the law 95/2006 on health care reform). The New Plan for Rare Diseases 2021-2027
Serbia	<ol style="list-style-type: none"> <li>1. The first National Program for rare disease for Republic of Serbia for 2020-2022 was adopted in 2019 and implemented from 2020 to 2022</li> <li>2. Registry for RD patients is developed in 2020 and national referent centers for rare diseases are informed to send relevant data</li> <li>3. Genetic testing for all RD patients (referred from 5 national reference centers for rare diseases) is paid by healthcare insurance fund of Re-</li> </ol>

	public of Serbia, and it is performed in the country (since 2021) 4. Newborn screening (previously including two disease phenylketonuria and congenital hypotireoidosis) is expanded to include cystic fibrosis and a pilot newborn screening for spinal muscular atrophy started in 2022
Slovakia	active participation in ERNs in the second call: EndoERN full member FM ERN Guard Heart AM ERN Lung FM ERN EuroBloodNet affiliated member AM ERN Eye AM ERN Ithaca FM MetabERN FM ERN PeadCan FM ERN Rita FM approved National plan for RD 2021 -2030 approved Action plan for RD 2021-2022 2023 newborn screening expansion + Severe immunodeficiency and spinal muscular atrophy
Slovenia	Establishment of new National Plan for RD and associated Action Plan 2022-2023.
Spain	-
Switzerland	Designation of the centers of reference and RD are more present in the public eye
The Netherlands	- The centers of expertise on RD and national involvement in ERNs - Policy letter of Ministry of Health on centers of expertise (early 2021) - Vision document of VSOP (Dutch Patients alliance on RD) on national strategy RD 2030 <a href="https://vsop.nl/media/uploads/file/Visiedocument%20NSZA%202030%20def.pdf">https://vsop.nl/media/uploads/file/Visiedocument%20NSZA%202030%20def.pdf</a> - Dutch National Mirror Group

### Focus on EU-13 Countries

As in the past editions of this series of documents, a dedicated analysis has been performed on the information furnished by the EU-13 Countries to all items of the survey. Two final questions reserved to EU-13 Countries on perceived obstacles and barriers in the RD field have been analysed as well.

#### General information

All ten EU-13 Countries participating in the survey (100%), declare to have a NP/NS for RD either active, expired, under renewal or under approval. More in detail, three (30%) declare to have a NP/NS for RD active and in force (Romania, Slovakia, Slovenia), five (50%) to have an expired NP /NS for RD (Bulgaria, Cyprus, Czech Republic, Estonia, Lithuania), one (10%) that a NP/NS for RD has been developed and is under approval (Malta), and one (10%) that the NP/NS for RD has been approved but is not active (Poland).

Two countries with an expired NP/NS for RD are in the process of renewal (Cyprus, Lithuania), while three countries did not start such renovation process (Bulgaria, Czech Republic, Estonia).

Below Table 14 shows the date of expiry of the NP/NS for RD with some specifications given by the countries.

**Table 14. Year of expiry of the NP/NS for RD of the EU-13 Countries declaring to have an expired NP/NS for RD in 2023<sup>32</sup>**

Bulgaria	The previous NP for RD in Bulgaria officially expired on December 31, 2013
Cyprus	The NP/NS expired in 2018, a revision process started in 2019 but this process did not conclude
Czech Republic	2020
Estonia	No data available from the survey
Lithuania	National plan for rare diseases, adopted in 2012, does not have a time frame, but it was accompanied by a list of measures for the period of 2013-2017

The first among the EU-13 responding countries to have an approved NP/NS for RD emerges to be Bulgaria (2008), followed by Czech Republic (2010), Slovenia (2011), Cyprus, Lithuania, Slovakia (2012), Estonia and Romania (2014), Poland (2021). Moreover, three countries (30%) specify to be at their second edition of NP/NS for RD (Romania, Slovakia, Slovenia), one country (10%) that the ten-year Strategy was accompanied by three National Action Plans until 2020 (Czech Republic) and one country (10%) that the not time-bound Plan was accompanied by a list of measures for the period 2013-2017 (Lithuania).

Of the nine countries with an approved NP/NS for RD, either active or expired, five (56%) inform that there is a periodical evaluation of the NP/NS for RD. This information is missing for Malta<sup>33</sup>.

Moreover, 90% of the surveys have been filled by persons directly involved in the implementation or development of the NP/NS for RD of their country (Bulgaria, Cyprus, Czech Republic, Estonia, Malta, Poland, Romania, Slovakia, Slovenia).

The following results show the alignment status of the NP/NS for RD of the responding EU-13 Countries with the four EJP RD Pillars.

#### Alignment status of NP/NS for RD with the activities promoted by the 4 EJP RD Pillars

##### **Pillar 1 - “National and International investments on research in the field of RD”**

When considering the initiatives promoted by Pillar 1, three countries (30%) show a positive alignment of the NP/NS for RD in respect to the promotion of both national

<sup>32</sup> Question addressed in the 2023 edition only to the countries with an expired NP/NS

<sup>33</sup> On this item the information is missing for Malta, as in this country the NP/NS for RD is under approval. The question has been addressed only to the countries declaring to have a NP/NS for RD, active, approved but not active or expired, and the percentages refer to the 9 responding countries

and transnational calls for research projects, as well as to the provision of investments to share knowledge (Cyprus, Lithuania, Slovenia).

The NP/NS for RD of five countries (50%) promotes national and transnational calls for research projects (Cyprus, Czech Republic, Lithuania, Romania, Slovenia), and of one country (10%) only of national calls (Slovenia).

In one country (10%) the NP/NS for RD foresees investments to share knowledge, but there is lack of support to national and/or transnational calls for research projects (Poland).

Finally, two countries (20%) refer the absence of the support of the NP/NS for RD in relation to the promotion of national and/or transnational calls for research projects, as well as to the provision of investments to share knowledge (Bulgaria, Estonia), and one country (10%) refers not to know about these items (Malta).

## **Pillar 2- - “Resources and services to foster research on RD”**

All investigated initiatives falling under Pillar 2 are foreseen by the NP/NS for RD of four countries (40%, Poland, Romania, Slovakia, Slovenia). In fact, the NP/NS for RD of these countries endorses the support to data repositories and tools for research on RD, to FAIR data, and towards the adoption of multidisciplinary holistic approaches.

Considering the support of the NP/NS for RD to the development and/or or implementation of data repositories and tools for research on RD, eight countries (80%) reply in the affirmative (Bulgaria, Estonia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia). Of these, six countries (60%) affirm that the NP/NS for RD supports the development (88%, Bulgaria, Estonia, Malta, Romania, Slovakia, Slovenia) and two countries (20%) both the development and the implementation of data repositories and tools for research on RD (Lithuania, Poland). In one country (10%) neither the development nor the implementation of data repositories and tools for research on RD is supported by the NP/NS for RD (Cyprus), and one country (10%) answers not to know (Czech Republic).

The topic receiving the support by 50% or more of the NP/NS for RD that endorse such means is represented by “Registries catalogue”, supported in seven countries (Bulgaria, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia). The other investigated topics are endorsed by less than 50% of the countries replying that their NP/NS for RD supports data repositories and tools for research on RD. For the detailed percentage rates of the support given by the NP/NS for RD regarding each investigated area of data repositories and tools for research on RD see Table 15.

**Table 15. Topics covered by the data repositories and tools for RD research that are supported by the NP/NS for RD of the EU-13 Countries, and countries covering them** <sup>34</sup>

<b>Registries catalogue, 7 countries (88%):</b> Bulgaria, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia
<b>Biobanks catalogue, 3 countries (38%):</b> Lithuania, Malta, Slovenia
<b>Ontologies and codification, 3 countries (38%):</b> Lithuania, Poland, Slovenia

<sup>34</sup> Percentages referring to the 8 countries declaring that the NP/NS for RD supports the development or both the development and implementation of data repositories and tools for research on RD

<b>OMIC services, 1 country (13%):</b> Lithuania
<b>Cell lines:</b> -
<b>Animal models:</b> -
<b>Semantic Standards, 1 country (13%):</b> Poland
<b>Support for clinical/translational research, 4 countries (50%):</b> Lithuania, Malta, Romania, Slovenia
<b>Access &amp; privacy control, 1 country (13%):</b> Lithuania
<b>Data deposition &amp; analysis, 3 countries (38%):</b> Estonia, Lithuania, Poland
<b>Tools, 1 country (13%):</b> Lithuania
<b>Other:</b> -

The NP/NS for RD of five countries (50%) supports FAIR data (Lithuania, Poland, Romania, Slovakia, Slovenia), while in eight countries (80%) it promotes the adoption of multidisciplinary/holistic approaches for RD (Bulgaria, Cyprus, Estonia, Lithuania, Poland, Romania, Slovakia, Slovenia).

The countries that do not have a NP/NS for RD supporting FAIR data are three (30%, Bulgaria, Cyprus and Estonia), while one country (10%) is provided by a NP/NS for RD that does not promote the adoption of multidisciplinary/holistic approaches for RD (Czech Republic).

The countries not knowing if their NP/NS for RD supports FAIR data are two (20%, Czech Republic, Malta), one of these (10%) does not know either if the NP/NS for RD promotes the adoption of multidisciplinary/holistic approaches (Malta).

### **Pillar 3- “Capacity building and empowerment”**

All ten EU-13 Countries (100%) that replied to the survey are provided by a NP/NS for RD that supports RD training activities (Bulgaria, Cyprus, Czech Republic, Estonia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia).

The RD training topics covered by 50% or more of the NP/NS for RD are represented by “Empowerment of the Patients”, (90%, Bulgaria, Cyprus, Czech Republic, Estonia, Luxembourg, Poland, Romania, Slovakia, Slovenia), “Registries”, (60%, Bulgaria, Malta, Poland, Romania, Slovakia, Slovenia) and “Online education courses”, (50%, Bulgaria, Cyprus, Czech Republic, Poland, Romania). The other investigated topics are endorsed by less than 50% of the countries replying that their NP/NS for RD supports RD trainings. For the detailed percentage rates of the support given by the NP/NS for RD regarding each investigated area of RD trainings see Table 16.

**Table 16. Topics covered by the training activities that are supported by the NP/NS for RD of the EU-13 Countries and countries covering them<sup>35</sup>**

<b>Data management, 3 countries (30%):</b> Lithuania, Malta, Poland
<b>Data quality, 3 countries (30%):</b> Czech Republic, Malta, Poland
<b>FAIR data, 1 country (10%):</b> Poland
<b>Standards and quality of genetics/genomics data in clinical practice and laboratories, 3 countries (30%):</b> Czech Republic, Lithuania, Poland

<sup>35</sup> Percentages referring to the countries replying “Yes” to the previous question

<b>Registries, 6 countries (60%):</b> Bulgaria, Malta, Poland, Romania, Slovakia, Slovenia
<b>Biobanks, 1 country (10%):</b> Poland
<b>Empowerment of the patients, 9 countries (90%):</b> Bulgaria, Cyprus, Czech Republic, Estonia, Luxembourg, Poland, Romania, Slovakia, Slovenia
<b>Online education courses, 5 countries (50%):</b> Bulgaria, Cyprus, Czech Republic, Poland, Romania
<b>Other, 1 country (10%):</b> Estonia

**Pillar 4- “Accelerated translation of research projects and improvement of outcomes of clinical studies”**

Taking the activities promoted by Pillar 4 into account, it arises that the NP/NS for RD of two countries (20%) promotes both the rapid translation of research in clinical studies and healthcare and the development of innovative methodologies tailored for clinical trials (Romania, Slovenia).

One additional country (10%) declares that the NP/NS for RD promotes the rapid translation of research results in clinical studies and healthcare (Lithuania).

The countries answering that their NP/NS for RD does not support neither the rapid translation of research results in clinical studies and healthcare nor the development of innovative methodologies tailored for clinical trials are five (50%, Bulgaria, Cyprus, Czech Republic, Estonia, Slovakia). The remaining two countries (20% Malta, Poland) answer “No” (Poland) to the first item, and “I don’t know” to the second item (Malta, Poland).

Alignment status of other relevant RD activities than the NP/NS for RD with the activities promoted by the 4 EJP RD Pillars

**Pillar 1- “National and International investments on research in the field of RD”**

Other public initiatives than the NP/NS for RD that promote national calls for research/networking in the field of RD are reported by three countries (30%, Cyprus, Romania, Slovenia), and private funding initiatives by one country (10%, Bulgaria). Other private initiatives for RD of this country promote also transnational calls for research/networking in the field of RD, whereas the lack of support by other public initiatives to transnational calls is reported by all countries.

Four countries (40%) do not have neither public nor private funding initiatives for national and transnational calls for research/networking in the field of RD (Czech Republic, Estonia, Lithuania, Slovakia), and two countries (20%) answer “I don’t know” to all items (Malta, Poland).

Regarding investments to share knowledge, no country refers of other public initiatives, whereas two countries (20%) report the existence of private funding initiatives (Bulgaria, Cyprus). The number of countries declaring not to know is of four (40%) for the public initiatives (Cyprus, Malta, Poland, Romania), and of three (30%) for the private initiatives (Malta, Poland, Romania).

## **Pillar 2- “Resources and services to foster research on RD”**

Only one country (10%) declares the presence of other public funding initiatives than the NP/NS for RD that support data repositories and tools for research on RD (Bulgaria), while five countries (50%) answer “No” to this item (Czech Republic, Estonia, Lithuania, Slovakia, Slovenia), and four countries (40%) not to know (Cyprus, Malta, Poland, Romania). The topic covered by the other public initiatives than the NP/NS for RD that support data depositories and tools for research on RD is represented by “Registries catalogues”. The other topics are not covered.

The same country appears to be the only provided by other private funding initiatives than the NP/NS for RD that support data repositories and tools for research on RD (Bulgaria). As for the other public initiatives, the topic covered by private funding initiatives that support data depositories and tools for research on RD is represented by “Registries catalogue”.

Hence, Bulgaria is the only country with funding initiatives in this area, both private and public, other than the NP/NS for RD.

Other national initiatives that support FAIR data are present in two countries (20%, Romania, Slovenia). Of the other eight countries (80%), four (40%) answer that there are no other initiatives than the NP/NS for RD that support FAIR data (Bulgaria, Czech Republic, Lithuania, Slovakia), and four countries (40%) not to know.

Below Table 17 shows by which means FAIR data are supported by other initiatives than the NP/NS for RD in the two countries.

**Table 17. EU-13 Countries declaring that other initiatives than the NP/NS for RD support FAIR data and specifications**

Romania	Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI) supports the FAIR database by the project FAIR - IMPACT.
Slovenia	Eliksir National HUB

Three countries (30%) refer of other national initiatives than the NP/NS for RD that promote the adoption of multidisciplinary holistic approaches for RD (Bulgaria, Romania, Slovenia), while in four countries (40%) this kind of support is not present (Czech Republic, Estonia, Lithuania, Slovakia), and three countries (30%) answer “I don’t know” to this item (Cyprus, Malta, Poland).

## **Pillar 3- “Capacity building and empowerment”**



Two countries (20%) reply that other initiatives than the NP/NS for RD support RD trainings (Bulgaria, Romania), four countries (40%) that no other initiatives than the NP/NS for RD support RD trainings (Czech Republic, Estonia, Lithuania, Slovakia, Slovenia) and three countries (30%) not to know (Cyprus, Malta, Poland).

Below Table 18 shows the topics covered by the RD trainings supported by other initiatives than the NP/NS for RD of the two countries (Bulgaria, Romania).

**Table 18. Topics covered by the training activities that are supported by other initiatives than the NP/NS for RD of the EU-13 Countries and countries covering them<sup>36</sup>**

<b>Data management, 1 country (50%):</b> Romania
<b>Data quality, 1 country (50%):</b> Romania
<b>FAIR data:</b> -
<b>Standards and quality of genetics/genomics data in clinical practice and laboratories:</b> Romania
<b>Registries, 1 country (50%):</b> Romania
<b>Biobanks:</b> -
<b>Empowerment of the patients, 2 countries (100%):</b> Bulgaria, Romania
<b>Online education courses, 2 countries (100%):</b> Bulgaria, Romania
<b>Other:</b> -

#### **Pillar 4- “Accelerated translation of research projects and improvement of outcomes of clinical studies”**

Regarding the items that investigate the activities related to Pillar 4, no country answers in the affirmative.

Five countries (50%) declare that there are no other initiatives than the NP/NS for RD that promote a rapid translation of research results in clinical studies and healthcare (Bulgaria, Czech Republic, Lithuania, Slovakia, Slovenia), and five countries (50%) that they do not know.

The question on the promotion by other initiatives of the development of innovative methodologies tailored for clinical trials obtained similar result. In fact, six countries (60%) answer that there is the lack of such initiatives (Bulgaria, Czech Republic, Estonia, Lithuania, Slovakia, Slovenia), and four countries (40%) not to know (Cyprus, Malta, Poland, Romania).

#### **Impact of the EJP RD activities at national level**

Seven EU-13 Countries (70%) inform that the EJP RD activities promoted, triggered, or helped to enforce RD undertakings that were not implemented or deemed so far in the country (Cyprus, Czech Republic, Lithuania, Malta, Poland, Romania, Slovakia). The topics on which EJP RD “Promoted, triggered, or helped to enforce RD undertakings that were not implemented or deemed so far in the country” are represented by (in descending order of frequency):

<sup>36</sup> Percentages referring to the two countries declaring that other initiatives than the NP/NS for RD support training activities for RD

- “Increased participation in national calls for research projects”
- “Increased participation in transnational calls for research projects” and “Support to the implementation of FAIR data”
- “Promotion of rapid translation of research results into clinical studies and healthcare”
- “Promotion of the development of innovative methodologies tailored for clinical trials”.

The same percentage rate (70%) can be observed for the countries replying that the EJP RD activities promoted, triggered, or helped the establishment of RD training activities (Bulgaria, Cyprus, Lithuania, Malta, Poland, Romania, Slovakia).

The topics on which the EJP RD “Promoted, triggered, or helped the establishment of RD training activities” are (in descending order of frequency):

- “Registries catalogue”
- “Biobanks catalogue”
- “Ontologies and codification”, and “Support for clinical/translational research”
- “Semantic standards”, “Access & privacy control”, “Data deposition and analysis” and “Tools”.

Finally, five countries (50%) declare that the EJP RD activities “Promoted, triggered, or helped the establishment and/or implementation of data repositories and tools for research in RD” (Cyprus, Czech Republic, Malta, Poland, Slovakia).

The topics on which the EJP RD promoted, triggered, or helped the establishment and/or implementation of data repositories and tools for research in RD are (in descending order of frequency):

- “Empowerment of the patients”, and “Online education courses”
- “Registries”
- “Data management”, and “Data quality”
- “FAIR data”, “Standards and quality of genetics/genomics data in clinical practice and laboratories”, and “Biobanks”

Globally 4 countries (40%) answered “Yes” to all three items exploring the impacts of the EJP RD at national level (Cyprus, Malta, Poland, Slovakia), seven countries (70%) to at least two items (Cyprus, Czech Republic, Lithuania, Malta, Poland, Romania, Slovakia), and eight countries (80%) to at least one item (Bulgaria, Cyprus, Czech Republic, Lithuania, Malta, Poland, Romania, Slovakia). Two countries (20%) answered “No” to all three items (Estonia, Slovenia).

Two questions of the survey have been dedicated only to EU-13 Country respondents, as in previous editions of the survey. Both questions allowed multiple choice.

Nine countries (90%) point “Funding” as the main obstacles/barrier for the development, improvement and translation of RD research results (Bulgaria, Cyprus, Czech Republic, Estonia, Lithuania, Malta, Poland, Romania, Slovakia), and further, eight countries (80%) select “Difficulties in accessing to national resources for funding research and development of RD projects” (Bulgaria, Cyprus, Lithuania, Malta, Romania, Poland, Slovakia, Slovenia). “Lack of options” has been indicated by two countries (20%, Malta, Romania), while “Language” is not perceived as a main obstacle/barrier.

Among the main obstacles and barriers for the participation in EU/International projects in the RD field, “Bureaucratic application on responding procedures” has been indicated by eight countries (80%, Bulgaria, Cyprus, Czech Republic, Estonia, Malta, Romania, Poland, Slovakia), “Quality of support provided by national contact points” by five countries (50%, Czech Republic, Malta, Romania, Poland, Slovenia), “Lack of information on funding opportunities” by four countries (40%, Cyprus, Malta, Romania, Slovakia), as well as “Limited links to potential partners” (40%, Bulgaria, Cyprus, Lithuania, Malta). “Irrelevance of programme topics and goals to own research agenda” has been pointed by one country (10%, Lithuania).

Below the Tables 19 and 20 summarise these results.

**Table 19. Main perceived obstacles and barriers for the development, improvement and translation of RD research results**

<b>Language:</b> -
<b>Funding, 9 countries (90%):</b> Bulgaria, Cyprus, Czech Republic, Estonia, Lithuania, Malta, Poland, Romania, Slovakia
<b>Difficulties in accessing to national resources for funding research and development of RD projects, 8 countries (80%):</b> Bulgaria, Cyprus, Lithuania, Malta, Romania, Poland, Slovakia, Slovenia
<b>Lack of options, 2 countries (20%):</b> Malta, Romania

**Table 20. Most important estimated obstacles and barriers for the participation in EU/International projects in the RD field**

<b>Lack of information on funding opportunities, 4 countries (40%):</b> Cyprus, Malta, Romania, Slovakia
<b>Limited links to potential partners, 4 countries (40%):</b> Bulgaria, Cyprus, Lithuania, Malta
<b>Bureaucratic application on responding procedures, 8 countries (80%):</b> Bulgaria, Cyprus, Czech Republic, Estonia, Malta, Romania, Poland, Slovakia
<b>Irrelevance of programme topics and goals to own research agenda, 1 country (10%):</b> Lithuania
<b>Quality of support provided by national contact points, 5 country (50%):</b> Czech Republic, Malta, Romania, Poland, Slovenia

## Summary of the 3 editions

### General information

In the period from October 2020 to end of March 2023, thirty-four countries have participated to the survey (Armenia, Austria, Belgium, Bulgaria, Canada, Cyprus, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Sweden, Spain, Switzerland, The Neth-

erlands, Turkey, UK)<sup>37</sup>. Target of the survey over the three editions were the EJP RD countries and Cyprus, as part of the EU-13 Countries.

In 2020, twenty-one countries participated to the survey (Bulgaria, Canada, Czech Republic, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Lithuania, Luxembourg, Portugal, Romania, Serbia, Slovakia, Spain, Sweden, The Netherlands, Turkey, UK), whereas in 2021 the number of participating countries has been of twenty-eight (Austria<sup>38</sup>, Armenia, Belgium, Bulgaria, Canada, Croatia, Czech Republic, Estonia, France, Georgia, Germany, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Slovakia, Spain, Sweden, The Netherlands, Turkey, UK)<sup>39</sup>, and of twenty-five in 2023 (Austria, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, France, Georgia, Germany, Israel, Italy, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Switzerland, The Netherlands).

Of the total thirty-four participating countries, thirteen countries (36%) took part in one edition (Armenia, Belgium, Croatia, Cyprus, Denmark, Hungary, Latvia, Malta, Norway, Slovenia, Sweden, Switzerland, UK), eight countries (22%) in two editions (Austria, Estonia, Georgia, Ireland, Lithuania, Poland, Slovakia, Turkey) thirteen countries (36%) in all three editions (Bulgaria, Canada, Czech Republic, France, Germany, Israel, Italy Luxembourg, Portugal, Romania, Serbia, Spain, The Netherlands).

Missing countries for these data collections are two countries (6%, Greece and Finland).

When considering the participation of the EU-13 Countries to the three editions of the survey, it appears that three countries (23%) participated to all three editions (Bulgaria, Czech Republic, Romania), four countries (31%) to two editions (Estonia, Lithuania, Poland, Slovakia), and six countries (46%) to at least one edition (Croatia, Cyprus, Hungary, Latvia, Malta, Slovenia).

All EU-13 Countries participated in at least one edition, although for Hungary only the data that a NP/NS for RD was under development in 2020 is available.

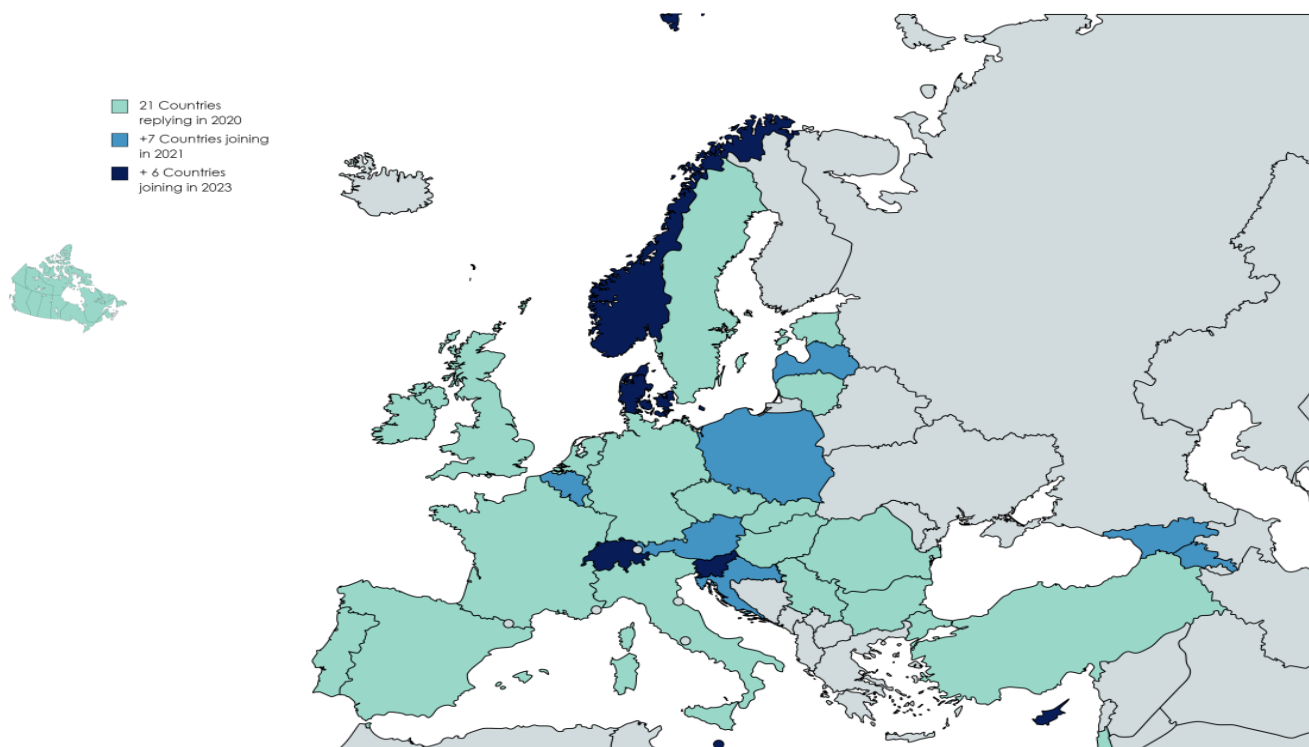
Figure 1 shows in different shades of blue the countries that joined the three editions of the survey.

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<sup>37</sup> Hungary and Sweden answered only to the first edition of the survey. Hungary was developing a NP/NS for RD at the time of the data collection and Sweden declared to have no NP/NS for RD. For both, no other information is available from the surveys.

<sup>38</sup> In 2021 Austria submitted a completed survey after the deadline; the answers given in 2021 were not included in D2.23 “Third analysis of national state of play and alignment process with EJP RD”, as well as in the results presented at the occasion of the strategic meeting with national policy makers of 8 July 2021, but will be included among the results of the 2021 edition in this document

<sup>39</sup> Given the short laps of time passed between the 2020 and 2021 editions of the survey (6 months), the outcomes of 2021 sum up the results obtained in 2020 and 2021, as written in D2.23 “Third analysis of national state of play and alignment process with EJP RD”. For the countries that did not give updates in 2021 the responses furnished in 2020 have still been considered as valid in 2021. Countries that did not give information regarding some topics in the 2021 edition of the survey have not been considered for the calculation of the relative percentages (Canada, Israel). Hungary and Sweden are not included as well, as specified in footnote 31



**Figure 1. Countries participating to the three editions of the survey over the period 2020 to 2023**

The above-described results have been summarised in the tables below.

**Table 21. Participation of the countries to the three editions of the survey (2020, 2021, 2023)<sup>40</sup>**

<sup>40</sup>Highlighted in blue the countries that participated in 3 editions of the survey, in pink the countries that participated in 2 editions, in yellow the countries that participated in one edition and in grey the countries who did not participate in any edition.

	2020 edition	2021 edition	2023 edition
Armenia		yes	
Austria		yes	Yes
Belgium		yes	
Bulgaria	yes	yes	Yes
Canada	yes	yes	Yes
Croatia		yes	
Cyprus			Yes
Czech Republic	yes	yes	Yes
Denmark			Yes
Estonia	yes		Yes
Finland			
France	yes	yes	Yes
Georgia		yes	Yes
Germany	yes	yes	Yes
Greece			
Hungary	yes		
Ireland	yes	yes	
Israel	yes	yes	Yes

	2020 edition	2021 edition	2023 edition
Italy	yes	yes	Yes
Latvia		yes	
Lithuania	yes		Yes
Luxembourg	Yes	yes	Yes
Malta			Yes
Norway			Yes
Poland		yes	Yes
Portugal	Yes	yes	Yes
Romania	Yes	yes	Yes
Serbia	Yes	yes	Yes
Slovakia	Yes		Yes
Slovenia			Yes
Spain	Yes	Yes	Yes
Sweden	Yes		
Switzerland			Yes
The Netherlands	Yes	Yes	Yes
Turkey	Yes	Yes	
UK	Yes		

#### **Number of participations to the 3 editions of the Survey of the targeted countries<sup>41</sup>**

**3 editions, 13 countries (36%):** Bulgaria, Canada, Czech Republic, France, Germany, Israel, Italy, Luxembourg, Portugal, Romania, Serbia, Spain, The Netherlands

**2 editions, 8 countries (22%):** Austria, Estonia, Georgia, Ireland, Lithuania, Poland, Slovakia, Turkey

**1 edition (36%):** Armenia, Belgium, Croatia, Cyprus, Denmark, Hungary, Latvia, Malta, Norway, Slovenia, Sweden, Switzerland, UK

**Missing countries, 13 countries (6%):** Greece, Finland

#### **EU-13 countries and number of participations to the survey**

**3 editions, 3 countries (23%):** Bulgaria, Czech Republic, Romania

**2 editions, 4 countries (31%):** Estonia, Lithuania, Poland, Slovakia

**1 edition, 6 countries (46%):** Croatia, Cyprus, Hungary, Latvia, Malta, Slovenia

In all, of the 34 countries that participated to the survey, it appears that in the period from 2 November 2020 to 31 of March 2023, thirty-two countries (97%) had a NP/NS for RD either active, expired, under renewal, under development or under approval, as summarised in Table 22 (Armenia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Georgia, Germany, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Switzerland, The Netherlands, Turkey, UK).

<sup>41</sup> Percentages referring to the 36 targeted countries

**Table 22. Details of the status of NP/NS for RD in all the surveyed countries (period 2 November 2020-31 March 2023)<sup>42</sup>**

Country	Year of approval	Year of expiry	Periodical evaluation	Under development
<b>ARMENIA</b>				Yes
<b>AUSTRIA</b>	2015	Not time-bound	yes	
<b>BELGIUM</b>	2014	Not time-bound		
<b>BULGARIA</b>	2008	2013		
<b>CANADA</b>				Yes
<b>CROATIA</b>	2015	2020		
<b>CYPRUS</b>	2012	2019	yes	Renewed version under development
<b>CZECH REPUBLIC</b>	2018 (last edition)	2020	yes	
<b>DENMARK</b>	2014	2019	yes	
<b>ESTONIA</b>	2014	2017		
<b>FRANCE</b>	2018 (last edition)	2022	yes	Renewed version under development
<b>GEORGIA</b>				Yes
<b>GERMANY</b>	2013	Not time-bound		
<b>HUNGARY</b>	2013	2020		
<b>IRELAND</b>	2014	2018	yes	
<b>ISRAEL<sup>43</sup></b>	No NP/NS for RD			
<b>ITALY</b>	2013	2016		Renewed version

<sup>42</sup> The table shows the most updated data available from the three editions of the survey and, where missing, from Hedley, V., Bottarelli, V., Weinman, A. et al. Shaping national plans and strategies for rare diseases in Europe: past, present, and future. *J Community Genet* 12, 207–216 (2021), <https://doi.org/10.1007/s12687-021-00525-4>

<sup>43</sup> In 2021 declares that the NP/NS for RD is under development, whereas in 2023 to have no NP/NS for RD

Country	Year of approval	Year of expiry	Periodical evaluation	Under development
				under development
<b>LATVIA</b>	2013	2020		
<b>LITHUANIA</b>	2012	Not time-bound; Plan of Actions under renewal	yes	
<b>LUXEMBOURG</b>	2018	2022	yes	
<b>MALTA</b>				Under approval
<b>NORWAY</b>	2021	Not time-bound	yes	
<b>POLAND</b>	2021	2023		
<b>PORTUGAL</b>	2015 (last edition)	2021	yes	
<b>ROMANIA</b>	2014	2020	yes	
<b>SERBIA</b>	2019	2022		Renewed version under development
<b>SLOVAKIA</b>	2021	2020	yes	
<b>SLOVENIA</b>	2022 (last edition)	2030	yes	
<b>SPAIN</b>	2009	Not time-bound	yes	
<b>SWEDEN</b>	No NP/NS for RD			
<b>SWITZERLAND</b>	2014	2019		
<b>THE NETHERLANDS</b>	2013	2018	yes	
<b>TURKEY</b>				Yes
<b>UK</b>	2021 (last edition)	2026	yes	



In Annex 3 the results for each year of the survey for all participating countries. As specified earlier in the document, the outcomes of 2021 sum up the results obtained in 2020 and 2021, given the short laps of time passed between the 2020 and 2021 editions of the survey (6 months). For the countries that did not give updates in 2021 the responses furnished in 2020 have still been considered as valid in 2021. Countries that did not give information regarding some topics in the 2021 edition of the survey have not been considered for the calculation of the relative percentages (Canada, Israel). Hungary and Sweden answered only to the first edition of the survey. Hungary was developing a NP/NS for RD at the time of the data collection and Sweden declared to have no NP/NS for RD. For both, no other information is available from the surveys, and the two countries have not been considered for the calculation of the percentages.

Annex 2 shows the most updated links to the NP/NS for RD available from the surveys for each country.

### Follow-up: comparison between the answers submitted by 19 countries participating in two or more editions of the survey

All the results presented in this section refer to changes appearing from the comparison of the answers submitted by the countries participating in two or more editions of the survey, with the exceptions of Ireland and Turkey, who submitted completed surveys both in 2020 and 2021 but not in 2023. This is motivated by the short time laps between the two first surveys and the absence of relevant changes in the submitted answers for Ireland and, for Turkey, also by the absence of information both on the NP/NS for RD that was under development, and on other relevant RD activities<sup>44</sup>.

The 19 countries analysed for comparison are: Austria, Bulgaria, Canada, Czech Republic, Estonia, France, Georgia, Germany, Israel, Italy, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Slovakia, Spain, The Netherlands.

The questions on the existence and status of a NP/NS for RD and the main questions on the alignment with the EJP RD Pillars of the NP/NS for RD and of other relevant RD activities constitute the objective of the comparison. Moreover, a dedicated analysis has been performed taking the EU-13 Countries into account.

#### **Is there an approved NP/NS for RD in your country?**

Summing up the results it emerges that, with regard to the existence of a NP/NS for RD, one country (5%) whose NP/NS for RD was under development in the period 2020/2021, results to have an approved NP/NS for RD in 2023 (Poland). In four coun-

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<sup>44</sup> UK submitted a survey only in 2020, but, as specified earlier in the document, the answers submitted in 2020 have been considered still valid for the analysis of 2021 for the countries that did not give updates in the second edition, given the short laps of time incurred between the two first editions of the surveys. As UK did not participate to the 2023 edition of the survey, it does not figure among the countries of this follow-up analysis. For Slovakia the outcomes of 2020 have still been considered as valid in 2021, even though Slovakia did not submit a survey in 2021, for the reasons reported above for UK. For the purposes of comparison of this document, only the answers submitted by this country in 2020 and 2023 have been taken into account.

For Israel the comparison has been performed only for other relevant RD initiatives than the NP/NS for RD, as at the time of the 2020 and 2021 surveys the NP/NS for RD was under development and no other information is available for the NP/NS for RD. In 2023 the country declared that there is no NP/NS for RD

tries (21%) the NP/NS for RD expired in the time span 2020/21- 2023 (Luxembourg, Portugal, Romania, Slovakia), and two countries (11%) remain in the state of development of a NP/NS for RD (Canada, Georgia). Four countries (21%) still have an expired NP/NS for RD (Bulgaria, Czech Republic, Estonia, The Netherlands), while two countries (11%) are renewing the expired NP/NS for RD (France, Serbia). Four countries (21%) have a NP/NS for RD without time-frame (Austria, Germany, Lithuania, Spain), one country (5%) is in the approval of the renewed NP/NS for RD (Italy), and one country (5%) who first declared that a NP/NS for RD was under development affirms that there is no NP/NS for RD (Israel).

These results on the existence of a NP/NS for RD in the periods 2020/21 and 2023 are summarised in Table 23.

**Table 23. Follow-up on the existence and status of s NP/NS for RD for the period 2020/21 vs 2023**

<b>Existence of a NP/NS for RD</b>	<b>2020/2021</b>	<b>2023</b>
<b>NP/NS for RD active, expired or under renewal</b>	<b>79 %</b> (15 countries, Austria, Bulgaria, Czech Republic, France, Georgia, Germany, Italy, Lithuania, Luxembourg, Portugal, Romania, Serbia, Slovakia, Spain, The Netherlands)	<b>84%</b> (16 countries, Austria, Bulgaria, Czech Republic, France, Georgia, Germany, Italy, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Slovakia, Spain, The Netherlands)
<b>No NP/NS for RD</b>	-	<b>5%</b> (1 country, Israel)
<b>NP/NS under development</b>	<b>21%</b> (4 countries, Canada, Georgia, Israel, Poland)	<b>11%</b> (2 countries, Canada, Georgia)

In the following part of this section the analyses have been focused on the variations in the replies per country over time in respect to the main items investigating the alignment status of the NP/NS for RD and of other national RD activities with the four EJP RD Pillars.

The variations are summarised as follows:

Positive variation, meaning that the NP/NS for RD/other RD activities did not support/promote the activity in question in the period 2020/21 or that there was lack of knowledge, but the situation has changed in a positive way in 2023.

Negative variation, meaning that the NP/NS for RD/other RD activities supported/promoted the activity in question in the period 2020/21, but the support/promotion is no longer in place in 2023, or that the latest answer indicates a change into a lack of knowledge.

Unvaried positive, meaning that the NP/NS for RD/other RD activities supported/promoted the activity in question in the period 2020/21 and the support/promotion is still in place in 2023.

Unvaried negative, meaning that the NP/NS for RD/other RD activities did not support/promote the activity in question in the period 2020/21, and that the situation has not changed in 2023, or that the lack of knowledge on the topic persists.

Missing, meaning no information for the country on the topic.

Alignment status of the NP/NS for RD with the activities promoted by the 4 EJP RD Pillars<sup>45</sup>

**Pillar 1 - “National and International investments on research in the field of RD”**

***Does the NP/NS for RD of your country promote national calls for research projects?***

<b>Positive variation, 6 countries (32%)</b>	Canada, Czech Republic, Lithuania, Portugal, Romania, Slovakia
<b>Negative variation, 1 country (5%)</b>	The Netherlands
<b>Unvaried positive, 5 countries (26%)</b>	France, Georgia, Germany, Luxembourg, Spain
<b>Unvaried negative, 6 countries (32%)</b>	Austria, Bulgaria, Estonia, Italy, Poland, Serbia
<b>Missing, 1 country (5%)</b>	Israel

***Does the NP/NS for RD of your country promote transnational calls for research projects?***

<b>Positive variation, 4 countries (21%)</b>	Canada, Lithuania, Romania, Slovakia
<b>Negative variation, 2 countries (10%)</b>	France, The Netherlands
<b>Unvaried positive, 6 countries (32%)</b>	Austria, Czech Republic, Germany, Luxembourg, Portugal, Spain
<b>Unvaried negative, 6 countries (32%)</b>	Bulgaria, Estonia, Italy, Georgia, Poland, Serbia
<b>Missing, 1 country (5%)</b>	Israel

***Does the NP/NS for RD of your country foresee investments to share knowledge?***

<b>Positive variation, 2 countries (11%)</b>	Canada, Poland
<b>Negative variation, 2 countries (11%)</b>	Bulgaria, The Netherlands
<b>Unvaried positive, 4 countries (21%)</b>	Georgia, Lithuania, Luxembourg, Spain
<b>Unvaried negative, 10 countries (53%)</b>	Austria, Czech Republic, Estonia, France, Germany, Italy, Portugal, Romania, Serbia, Slovakia
<b>Missing, 1 country (5%)</b>	Israel

From the comparison of the results it appears that regarding the promotion of national calls for research projects by the NP/NS for RD, six countries (32%) show a positive variation, meaning that, while in the period 2021/21 the NP/NS for RD did not foresee such promotion, in 2023 the situation has evolved towards the presence of this kind of action (Canada, Czech Republic, Lithuania, Portugal, Romania, Slovakia). A positive variation can be observed also regarding the promotion of transnational calls by the NP/NS for RD of 4 countries (21%, Canada, Lithuania, Romania, Slovakia),

<sup>45</sup> For all the items on the alignment status of the NP/NS for RD with the four EJP RD Pillars the information is lacking for Israel, as the country declares in 2023 not to be provided by a NP/NS for RD active, expired or under development (whereas in 2020 and 2021 the country declared that a NP/NS for RD was under development). The country figures therefore in all tables regarding the NP/NS for RD as missing country, representing 5% of the participating countries. Information is available for the other national RD activities.

three of which (18%) figure also among the countries whose NP/NS for RD enhanced the promotion of national calls for research projects (Canada, Lithuania, Slovakia).

A smaller amount of countries (21%) shows a positive variation in respect to the provision of investments to share knowledge, measure that has been added to the NP/NS for RD of two countries (Canada, Poland).

In all, one country (5%) shows a positive variation in the alignment of the NP/NS for RD with all three investigated areas of Pillar 1 (Canada).

In six countries (32%) the absence of the promotion of national calls for research projects by the NP/NS for RD is still observable (Austria, Georgia, Germany, Luxembourg, Spain), whereas in five countries (26%) the favourable situation in respect to the promotion of national calls for research projects by the NP/NS for RD remained unvaried (France, Georgia, Germany, Luxembourg, Spain). For one country (5%) there has been a negative variation in this field (The Netherlands).

Summarising, an equal amount NP/NS for RD enhanced the promotion of national calls for research projects (32%) or kept a positive situation (32%).

Looking at the promotion of transnational calls for research projects by the NP/NS for RD, for which the proportion of positive variations has been cited above, there is an equal amount of countries with an unvaried situation, that for six countries (32%) consists in the continuance of the action (Austria, Czech Republic, Germany, Luxembourg, Portugal, Spain) and for six countries (32%) in the persisting lack of promotion (Bulgaria, Estonia, Italy, Georgia, Poland, Serbia).

Moreover, in two countries (11%) for which in the period 2020/21 the promotion of transnational calls for research projects was foreseen by the NP/NS for RD, this action is no longer reported (France, The Netherlands).

A global less favourable situation emerges for the area of investments to share knowledge, with two countries (11%) showing a negative variation (Bulgaria, The Netherlands), and 10 countries (53%) the persistence of lack of support by the NP/NS for RD in this field (Austria, Czech Republic, Estonia, France, Germany, Italy, Portugal, Romania, Serbia, Slovakia). Four countries (21%) keep a positive position in this area (Georgia, Lithuania, Luxembourg, Spain) and two countries (11%) gain a positive variation (Canada, Poland).

In general, the most favourable condition with regard to the alignment of the NP/NS for RD of the 19 target countries with the activities investigated for Pillar 1 appears towards the promotion of national calls for research projects that continues to be present in 26% of the countries and has been newly adopted in 32% of the countries, with a global presence in more than 50% (58%) of the NP/NS for RD of the 19 countries in 2023. Also, the promotion of transnational calls for research projects sees a global presence in more than 50% of the NP/NS for RD (21% of positive variation and 32% of unvaried positive situations), even if in a lower amount (51%).

Differently, for the provision of investments to share knowledge by the NP/NS for RD, 64% of the countries show either a negative variation (11%) or an unvaried negative condition (53%).

**Pillar 2<sup>46</sup>- “Resources and services to foster research on RD”**

**Does the NP/NS for RD of your country support data repositories and tools for research on RD?**

<b>Positive variation, 3 countries (16%)</b>	Estonia, Poland, Slovakia
<b>Negative variation, 5 countries (26%)</b>	Austria, Czech Republic, Luxembourg, Serbia, The Netherlands
<b>Unvaried positive, 8 countries (42%)</b>	Bulgaria, France, Georgia, Germany, Italy, Lithuania, Romania, Spain
<b>Unvaried negative: 1 (5%)</b>	Portugal
<b>Missing, 2 countries (11%)</b>	Canada, Israel

**Does the NP/NS for RD of your country support FAIR\* data? (Findable, Accessible, Interoperable, Reusable)**

<b>Positive variation, 5 countries (26%)</b>	Italy, Lithuania, Poland, Romania, Slovakia
<b>Negative variation, 1 country (5%)</b>	Spain
<b>Unvaried positive, 2 countries (11%)</b>	France, Germany
<b>Unvaried negative, 9 countries (47%)</b>	Austria, Bulgaria, Czech Republic, Estonia, Georgia, Luxembourg, Portugal, Serbia, The Netherlands
<b>Missing, 2 countries (11%)</b>	Canada, Israel

**Does the NP/NS for RD promote the adoption of multidisciplinary/holistic approaches for RD?**

<b>Positive variation, 2 countries (11%)</b>	Estonia, Slovakia
<b>Negative variation, 1 country (5%)</b>	The Netherlands
<b>Unvaried positive, 13 countries (68%)</b>	Austria, Bulgaria, France, Georgia, Germany, Italy, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Spain
<b>Unvaried negative, 1 country (5%)</b>	Czech Republic
<b>Missing, 2 countries (11%)</b>	Canada, Israel

Considering the alignment of the NP/NS for RD with the activities of Pillar 2, three countries (16%) reveal the variation in a positive sense with reference to the support to data repositories and tools for research on RD (Estonia, Poland, Slovakia). The NP/NS for RD of eight countries (42%) show to maintain the presence of the support over the reference period 2020/21-2023 (Bulgaria, France, Georgia, Germany, Italy, Lithuania, Romania, Spain), while in five countries (26%) the loss of this initiative has emerged (Austria, Czech Republic, Luxembourg, Serbia, The Netherlands). Finally, the NP/NS for RD of one country (5%) seems to stay in the condition of not supporting such initiative (Portugal).

Moving to the support to FAIR data, the NP/NS for RD of five countries (26%) demonstrates a positive evolution (Italy, Lithuania, Poland, Romania, Slovakia) and in the

<sup>46</sup> Regarding the activities of Pillar 2 the comparison is not possible for Canada, as information is missing for this Pillar in the surveys 2020/21. Information is missing for Israel as described previously.

NP/NS for RD the favourable condition remains unchanged for two countries (11%, France, Germany).

About the absence of the support of the NP/NS for RD to FAIR data, the status remains unaltered for nine countries (47%, Austria, Bulgaria, Czech Republic, Estonia, Georgia, Luxembourg, Portugal, Serbia, The Netherlands), and for one country (5%) there has been a shift from the presence to the absence of support (Spain).

Regarding the last item referring to Pillar 2, the gain of adoption of multidisciplinary/holistic approaches for RD can be observed in the NP/NS for RD of two countries (11%, Estonia, Slovakia), whereas in the NP/NS for RD of one country (5%) a loss appears to be occurred (The Netherlands). The NP/NS for RD of thirteen countries (68%) remain in the condition of promoting multidisciplinary/holistic approaches for RD (Austria, Bulgaria, France, Georgia, Germany, Italy, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Spain), and of one country (5%) in the condition of lack of promotion (Czech Republic).

Altogether, the area in which the NP/NS for RD have mostly augmented their endorsements within the investigated topics of Pillar 2 appears to be towards the support of FAIR data, although through the period 2020/21-2023 the proportion of NP/NS for RD that do not support (47%) and no longer support (5%) FAIR data exceeds the proportion of NP/NS for RD that previously and recently started to support FAIR data (11% and 26% respectively).

The support of the NP/NS for RD to data repositories and tools for research on RD has demonstrated less augmentation than the support to FAIR data, but it nevertheless appears to have reached overall a backing from more than 50% of the NP/NS for RD when summing the NP/NS for RD that already supported such activities (42%) and those that recently initiated to do so (16%).

Finally, the area that registered less a positive variation is the support of the NP/NS for RD to multidisciplinary/holistic approaches for RD, that nonetheless shows a good starting condition with 68% of the countries already enforcing the support in 2020/21, and two NP/NS for RD that joined (11%) in the support in 2023.

### **Pillar 3<sup>47</sup>- “Capacity building and empowerment”**

#### **Does the NP/NS for RD of your country promote training activities for RD?**

<b>Positive variation, 3 countries (16%)</b>	Austria, Estonia, Slovakia
<b>Negative variation, 1 country (5%)</b>	Italy
<b>Unvaried positive, 12 countries (63%)</b>	Bulgaria, Czech Republic, France, Georgia, Germany, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Spain
<b>Unvaried negative, 1 country (5%)</b>	The Netherlands
<b>Missing, 2 countries (11%)</b>	Canada, Israel

Exploring the variation in the support of the NP/NS for RD in respect to RD trainings, the already positive condition of twelve NP/NS for RD (63%, Bulgaria, Czech Republic, France, Georgia, Germany, Lithuania, Luxembourg, Poland, Portugal, Romania, Ser-

<sup>47</sup> Same consideration as footnote 41 for Canada and Israel

bia, Spain) has been enhanced with further three NP/NS for RD (16%) furnishing the support (Austria, Estonia, Slovakia). On the other hand, two countries (11%) demonstrate the persistence of lack of support (5%, The Netherlands) or loss of support (5%, Italy).

**Pillar 4<sup>48</sup>- “Accelerated translation of research projects and improvement of outcomes of clinical studies”**

**Does the NP/NS for RD of your country promote a rapid translation of research results in clinical studies and healthcare?**

<b>Positive variation, 4 countries (21%)</b>	Germany, Italy, Lithuania, Slovakia
<b>Negative variation, 2 country (11%)</b>	Czech Republic, The Netherlands
<b>Unvaried positive, 4 countries (21%)</b>	France, Georgia, Romania, Spain
<b>Unvaried negative, 7 countries (37%)</b>	Austria, Bulgaria, Estonia, Luxembourg, Poland, Portugal, Serbia
<b>Missing, 2 countries (11%)</b>	Canada, Israel

**Does the NP/NS for RD of your Country promote the development of innovative methodologies tailored for clinical trials?**

<b>Positive variation, 1 country (5%)</b>	Romania
<b>Negative variation, 2 countries (11%)</b>	Italy, Lithuania
<b>Unvaried positive -</b>	-
<b>Unvaried negative, 14 countries (73%)</b>	Austria, Bulgaria, Czech Republic, Estonia, France, Georgia, Germany, Italy, Luxembourg, Poland, Portugal, Serbia, Slovakia, Spain, The Netherlands
<b>Missing, 2 countries (11%)</b>	Canada, Israel

Coming to the initiatives falling under Pillar 4, in four countries (21%, Germany, Italy, Lithuania, Slovakia) a positive variation towards the promotion of the NP/NS for RD of the rapid translation of research results in clinical studies and healthcare emerges, which adds to the unvaried positive condition of other four countries (21%, France, Georgia, Romania, Spain). In seven countries (37%) the situation of the lack of promotion by the NP/NS for RD of this type of actions remains unvaried (Austria, Bulgaria, Estonia, Luxembourg, Poland, Portugal, Serbia), while for two countries (11%) a negative variation has been observed (Czech Republic, The Netherlands).

Less variability can be observed regarding the promotion of the development of innovative methodologies tailored for clinical trials by the NP/NS for RD. One single country (5%) started this kind of activity, being the only of the 19 countries provided by a NP/NS for RD that promotes the development of innovative methodologies tailored for clinical trials (Romania), as 14 countries (73%) show not to promote this kind of activity both in the period 2020/21 and 2023 (Austria, Bulgaria, Czech Republic, Estonia, France, Georgia, Germany, Luxembourg, Poland, Portugal, Serbia, Slovakia,

<sup>48</sup> Same consideration as footnote 41 for Canada and Israel

Spain, The Netherlands) and two countries (11%) not to continue the promotion (Italy, Lithuania).

Alignment status of other RD initiatives than the NP/NS for RD with the activities promoted by the 4 EJP RD Pillars

**Pillar 1- “National and International investments on research in the field of RD”**

Coming to the alignment process with other relevant RD activities than the NP/NS for RD, comparisons have been made between superposable questions of the three editions of the survey.

**Are there other public funding initiatives for research/networking in the field of RD in your country, apart from the NP/NS for RD?**<sup>49</sup>

<b>Positive variation, 1 country (5%)</b>	The Netherlands
<b>Negative variation, 8 countries (42%)</b>	Czech Republic, Estonia, France, Germany, Italy, Luxembourg, Poland, Portugal
<b>Unvaried positive, 4 countries (21%)</b>	Canada, Romania, Slovakia, Spain
<b>Unvaried negative, 6 countries (32%)</b>	Austria, Bulgaria, Georgia, Israel, Lithuania, Serbia
<b>Missing, -</b>	-

**Are there private funding initiatives for research/networking in the field of RD in your country?**

<b>Positive variation, 1 country (5%)</b>	Bulgaria
<b>Negative variation, 4 countries (21%)</b>	France, Israel, Lithuania, Portugal
<b>Unvaried positive, 5 countries (26%)</b>	Canada, Germany, Italy, Spain, The Netherlands
<b>Unvaried negative, 9 countries (47%)</b>	Austria, Estonia, Georgia, Luxembourg, Poland, Romania, Serbia, Slovakia
<b>Missing: -</b>	-

From the comparisons it emerges that an enhancement regarding other public funding initiatives for research/networking has been observed for one country (5%, The Netherlands), while eight countries (42%) went through a negative variation (Czech Republic, Estonia, France, Germany, Italy, Luxembourg, Poland, Portugal). Other six countries (32%) never showed an alignment in this area in the period 2020/21 and 2023 (Austria, Bulgaria, Georgia, Israel, Lithuania, Serbia), whereas four countries (21%) maintained a positive condition (Canada, Romania, Slovakia, Spain).

One country (5%) declares to have newly adopted other private funding initiatives for research/networking (Bulgaria), and five countries (26%) to continue the en-

<sup>49</sup> As in the 2020 edition of the survey, and in the elaboration of the updates in 2021 there has been no distinction between national and international activities at public/private level, the percentages reported in the table represent a global presence of other activities than those promoted by the NP/NS for RD



dorsement of this kind of undertakings (Canada, Germany, Italy, Spain, The Netherlands). On the other hand, four countries (21%) no longer declare the presence of such activities (France, Israel, Lithuania, Portugal) and nine countries (47%) that these activities were not implemented neither in 2020/21 nor in 2023 (Austria, Estonia, Georgia, Luxembourg, Poland, Romania, Serbia, Slovakia).

The situation regarding other relevant RD activities than the NP/NS for RD for research/networking appears to be therefore nearly unvaried during the period 2020/21-2023, with most countries not promoting this kind of initiatives, at public and/or at private level.

## **Pillar 2- “Resources and services to foster research on RD”**

### **Are there other public initiatives, than the NP/NS for RD of your country, that support data repositories and tools for research on RD?**

<b>Positive variation: -</b>	-
<b>Negative variation, 3 countries (16%)</b>	Czech Republic, France, Italy
<b>Unvaried positive, 5 countries (26%)</b>	Bulgaria, Canada, Serbia, Spain, The Netherlands
<b>Unvaried negative, 11 countries (58%)</b>	Austria, Estonia, Georgia, Germany, Israel, Lithuania, Luxembourg, Poland, Portugal, Romania, Slovakia
<b>Missing: -</b>	-

### **Are there other private initiatives of your country, that support data repositories and tools for research on RD?**

<b>Positive variation, 2 countries (11%)</b>	Germany, Spain
<b>Negative variation, 1 country (5%)</b>	Portugal
<b>Unvaried positive, 3 countries (16%)</b>	Bulgaria, Italy, The Netherlands
<b>Unvaried negative, 13 countries (68%)</b>	Austria, Canada, Czech Republic, Estonia, France, Georgia, Israel, Lithuania, Luxembourg, Poland, Romania, Serbia, Slovakia
<b>Missing</b>	-

### **Are there other national initiatives for RD, than the NP/NS, that support FAIR\* data? (\*Findable, Accessible, Interoperable, Reusable)**

<b>Positive variation, 2 countries (11%)</b>	Portugal, Romania
<b>Negative variation, 5 countries (26%)</b>	Canada, Czech Republic, France, Germany, Luxembourg
<b>Unvaried positive, 2 countries (11%)</b>	Italy, The Netherlands
<b>Unvaried negative, 10 countries (52%)</b>	Austria, Bulgaria, Estonia, Georgia, Israel, Lithuania, Poland, Serbia, Slovakia, Spain
<b>Missing: -</b>	-

### **Are there other national initiatives, than the NP/NS for RD, that promote the adoption of multidisciplinary approaches for RD?**

<b>Positive variation, 1 country (5%)</b>	The Netherlands
<b>Negative variation, 4 countries (21%)</b>	France, Germany, Lithuania, Portugal

<b>Unvaried positive, 4 countries (21%)</b>	Bulgaria, Canada, Italy, Romania
<b>Unvaried negative, 10 countries (53%)</b>	Austria, Czech Republic, Estonia, Georgia, Israel, Luxembourg, Poland, Serbia, Slovakia, Spain
<b>Missing: -</b>	-

No country shows a positive variation in the field of other public funding initiatives than the NP/NS for RD that support data repositories and tools for research on RD. Five countries (26%) remain in the condition of implementing these activities (Bulgaria, Canada, Serbia, Spain, The Netherlands) while the same seem to be no longer in place in three countries (16%, Czech Republic, France, Italy), and to have not been adopted in the period 2020/21 or 2023 by eleven countries (58% Austria, Estonia, Georgia, Germany, Israel, Lithuania, Luxembourg, Poland, Portugal, Romania, Slovakia).

Shifting to other private initiatives to support data repositories and tools for research on RD, two countries (11%) gained activities in this field (Germany, Spain) and three countries (16%) continue to implement these sorts of initiatives (Bulgaria, Italy, The Netherlands). An unvaried condition of absence of private initiatives can be found for thirteen countries (68%, Austria, Canada, Czech Republic, Estonia, France, Georgia, Israel, Lithuania, Luxembourg, Poland, Romania, Serbia, Slovakia), while one country (5%) no longer implements them (Portugal).

With regard to the support to FAIR data by other initiatives than the NP/NS for RD, a variation in a positive sense has been detected in two countries (11%, Portugal, Romania), and a stable positive situation in other two countries (11%, Italy, The Netherlands). Other initiatives supporting FAIR data continue to be absent in ten countries (52%, Austria, Bulgaria, Estonia, Georgia, Israel, Lithuania, Poland, Serbia, Slovakia, Spain), and five countries (26%) discontinued these initiatives (Canada, Czech Republic, France, Germany, Luxembourg).

The last item addressed at exploring the other RD initiatives than the NP/NS for RD related to Pillar 2 activities, namely towards the adoption of multidisciplinary holistic approaches for RD, shows the new adoption of such activities in one country (5%, The Netherlands) and the constant favourable condition in four countries (21%, Bulgaria, Canada, Italy, Romania). An unvaried absence emerges in ten countries (53%, Austria, Czech Republic, Estonia, Georgia, Israel, Luxembourg, Poland, Serbia, Slovakia, Spain), and a disruption in four countries (21%, France, Germany, Lithuania, Portugal).

In general, it appears that regarding other relevant RD activities than the NP/NS for RD in the areas of Pillar 2, most of the countries don't have other relevant activities, with six countries (32%) answering to have never endorsed such activities in all items (Austria, Estonia, Georgia, Israel, Poland, Slovakia).

**Are there other initiatives, than the NP/NS for RD, that support training activities for RD?**

<b>Positive variation, 1 country (5%)</b>	Romania
<b>Negative variation, 6 countries (32%)</b>	Canada, Czech Republic, Germany, Lithuania, Slovakia, Spain
<b>Unvaried positive, 5 countries (26%)</b>	Bulgaria, Italy, Portugal, Serbia, The Netherlands
<b>Unvaried negative, 7 countries (37%)</b>	Austria, Estonia, France, Georgia, Israel, Luxembourg, Poland

<b>Missing: -</b>	-
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One country (5%) newly started to implement the support of RD trainings through initiatives other than the NP/NS for RD, and five countries (26%) continue to promote such activities (Bulgaria, Italy, Portugal, Serbia, The Netherlands). The discarding of RD trainings supported by other initiatives than the NP/NS for RD emerges for six countries (32% Canada, Czech Republic, Germany, Lithuania, Slovakia, Spain), whereas seven countries (37%) remain in an unvaried condition of lack of support (Austria, Estonia, France, Georgia, Israel, Luxembourg, Poland). Altogether, 69% of the countries result in the position of either an unvaried negative situation of absence (37%) or in a discontinuation of RD trainings (32%).

**Are there other initiatives, than the NP/NS for RD, that promote a rapid translation of research results in clinical studies and healthcare?**

<b>Positive variation, 1 country (5%)</b>	Serbia
<b>Negative variation, 2 countries (11%)</b>	Canada, Portugal
<b>Unvaried positive, 2 countries (11%)</b>	Italy, The Netherlands
<b>Unvaried negative, 14 countries (73%)</b>	Austria, Bulgaria, Czech Republic, Estonia, France, Georgia, Germany, Israel, Lithuania, Luxembourg, Poland, Romania, Slovakia, Spain
<b>Missing: -</b>	-

The last item, falling under Pillar 4 and exploring the presence of other activities than the NP/NS for RD that promote a rapid translation of research results in clinical studies and healthcare indicates the attainment of activities in one country (5%, Serbia), the persistence in two countries (11%, Italy, The Netherlands), a loss in two countries (11%, Canada, Portugal) and an unvaried condition of absence in fourteen countries (73%, Austria, Bulgaria, Czech Republic, Estonia, France, Georgia, Germany, Israel, Lithuania, Luxembourg, Poland, Romania, Slovakia, Spain). As for Pillar 1 and Pillar 2, the absence of other initiatives for Pillar 4 can be observed in 68% or more of the countries in the relatives' fields of actions.

**EU-13 Countries**

The comparison for the EU-13 Countries that participated in two or more editions of the survey has been performed on the following 7 countries: Bulgaria, Czech Republic, Estonia, Lithuania, Poland, Romania, Slovakia.

**Alignment process of other RD initiatives than the NP/NS for RD with activities promoted by the 4 EJP RD Pillars**

**Pillar 1 - "National and International investments on research in the field of RD"**

Regarding the alignment of the NP/NS for RD with the actions of Pillar 1 it arises that three countries (43%) enhanced the promotion of national calls for research projects (Czech Republic, Lithuania, Slovakia), adding though to one country (14%) that promoted these calls formerly (Romania). For three countries (43%) the lack of promo-

tion remains unaltered (Bulgaria, Estonia, Poland) while no country has lost such initiatives.

Two countries gained also in the promotion of transnational calls for research projects (Lithuania, Slovakia), showing though a positive variation both at national and transnational level.

Two other countries continued in the effort of promotion of transnational calls for research projects (Czech Republic, Romania), whereas in three countries (Bulgaria, Estonia, Poland) the promotion seems to be no longer in place.

Finally, less variation can be observed moving to the provision of investments to share knowledge by the NP/NS for RD, as one country (14%) reveals a positive variation (Poland), one country (14%) and unvaried positive state (Lithuania), one country (14%) a loss (Bulgaria) and four countries (58%) a perduring absence of such initiatives (Czech Republic, Estonia, Romania, Slovakia).

### **Pillar 2- “Resources and services to foster research on RD”**

Shifting to the support to data repositories and tools for research on RD by the NP/NS for RD, a global positive frame emerges, as three countries (43%) demonstrate a positive change (Estonia, Poland, Slovakia), and other three countries (43%) pursued their activities in this field (Bulgaria, Lithuania, Romania). One country (14%) refers of the loss in these efforts (Czech Republic).

For the support to FAIR data by the NP/NS for RD four countries (57%) changed from the absence to the support of FAIR data (Lithuania, Poland, Romania, Slovakia). On the other side, three countries (43%) that previously implemented such support stopped in this effort (Bulgaria, Czech Republic, Estonia).

Finally, towards the promotion of multidisciplinary holistic approaches for RD by the NP/NS for RD, most of the countries appear either in the condition of having newly adopted such measures (29%, Estonia, Slovakia) or in the persistence of this activity (57%, Bulgaria, Lithuania, Poland, Romania), though one country (14%) reveals to have stopped this endorsement (Czech Republic).

### **Pillar 3- “Capacity building and empowerment”**

A fully positive condition arises regarding the support of the NP/NS for RD in respect to training activities as all countries demonstrate the presence of such efforts. For two countries (29%) the support represents a new achievement (Estonia, Slovakia), and for five countries (71%) the continuation of already existing initiatives.

### **Pillar 4- “Accelerated translation of research projects and improvement of outcomes of clinical studies”**

Coming to the promotion by the NP/NS for RD of the rapid translation of research results in clinical studies and healthcare, an overall condition of shortage appears, as one country (14%) declares the new adoption of measures in this field (Lithuania),

one country (14%) the continuation (Romania), while four countries (58%) reveal an unvaried absence of such initiatives (Bulgaria, Estonia, Poland, Slovakia) and another country (14%) the loss (Czech Republic).

Not very differently the condition when considering the development of innovative methodologies tailored for clinical trials, as one country refers of a positive variation (14%), being though the only country showing initiatives in this area (Romania), whereas one country (14%) registers a loss (Lithuania) and five countries (72%) the persistence of undertakings at this level (Bulgaria, Czech Republic, Estonia, Poland, Slovakia).

In this Pillar 72% or more of the countries show a lack of alignment of the NP/NS for RD, with five countries (71%) not supporting neither the promotion of the rapid translation of research results in clinical studies and healthcare, nor the development of innovative methodologies tailored for clinical trials (Bulgaria, Czech Republic, Estonia, Poland, Slovakia).

### **Alignment process of other RD initiatives than the NP/NS for RD with activities promoted by the 4 EJP RD Pillars <sup>50</sup>**

#### **Pillar 1- “National and International investments on research in the field of RD”**

In respect to the support of other public initiatives than the NP/NS for RD for research/networking in the RD field, no country shows an enhancement, one country shows (14%) the continuation of the undertakings (Romania), four countries (57%) an interruption (Czech Republic, Estonia, Poland, Slovakia) and two countries (29%) the persistence of the absence (Bulgaria, Lithuania).

Looking at the support of private initiatives for research/networking in the RD field, one country (14%) started the engagement in this area (Bulgaria), representing the only country that actually endorses this support. In fact, one other country (14%) has interrupted these actions (Lithuania) and the other five countries (72%) show an absence earlier and presently (Czech Republic, Estonia, Poland, Romania, Slovakia).

Globally a lack of undertakings at public and private level emerges regarding private or other public initiatives than the NP/NS for RD in the framework of Pillar 1.

#### **Pillar 2- “Resources and services to foster research on RD”**

Data repositories and tools for research on RD seem to receive limited support by private and by other public initiatives than the NP/NS for RD, as no positive variations have been observed and only one country (14%) keeps a positive situation for both kind of initiatives (Bulgaria). Six countries (68%) remain in the situation of lack of other public initiatives (Czech Republic, Estonia, Lithuania, Poland, Romania, Slovakia). One country (14%) discontinued the support of private initiatives for data repositories

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<sup>50</sup> As in the 2020 edition of the survey, and in the elaboration of the updates in 2021 there has been no distinction between national and international activities at public/private level, the percentages reported in the tables represent a global presence of other activities than those promoted by the NP/NS for RD on the specific item

and tools (Czech Republic) and five countries (72%) remain in the absence of these private initiatives (Estonia, Lithuania, Poland, Romania, Slovakia).

To continue the assessment of the activities falling under Pillar 2, one country (14%) moved towards the support to FAIR data by other initiatives than the NP/NS for RD (Romania), one country lost these types of initiatives (Czech Republic), and five countries (72%) stopped to endorse them (Bulgaria, Estonia, Lithuania, Poland, Slovakia). The emerging picture shows therefore a general absence of other initiatives for the support to FAIR data, that affects 86% of the countries.

Finally, no positive variation can be observed for the adoption of multidisciplinary/holistic approaches for RD by other initiatives than the NP/NS for RD. Three countries (43%) persist in the availability of this kind of activities (Bulgaria, Czech Republic, Romania), whereas one country (14%) ceased to do so (Lithuania), and three countries (43%) remain in an unvaried condition of absence.

### **Pillar 3- “Capacity building and empowerment”**

The new adoption of other initiatives than the NP/NS for RD supporting RD trainings has been observed in one country (14%, Romania), whilst in one other country (14%) these activities were already in place earlier, and continue to be supported (Bulgaria). Three countries (43%) evidence the discontinuation in these initiatives (Czech Republic, Lithuania, Slovakia), and two countries (29%) of not having adopted them, earlier or recently (Estonia, Poland).

### **Pillar 4- “Accelerated translation of research projects and improvement of outcomes of clinical studies”**

Finally, the comparison between the answers submitted regarding other initiatives that promote a rapid translation of research results in clinical studies and healthcare outline a 100% condition of persisting absence of such undertakings.

Regarding the main perceived obstacles and barriers for the development, improvement and translation of RD research results in the EU-13 Countries, there have been some improvements in the “Options of exploitation of research results at national level”, that is no longer indicated as barrier from one of the two countries that pointed this issue in 2020/21. There have been also advancements for the country that indicated “Language” as barrier in 2020/21 and that no longer pointed this as an obstacle.

For the points that have shown an increase in the perception of criticality, it emerged that “Funding” is still an obstacle, indicated by all countries in 2023, that is one more country than in 2020/21, whereas two more countries than in 2020/21 have indicated in 2023 “Difficulties in accessing to national resources for funding of research and development of RD projects”.

The results are summarised in Table 24.

**Table 24. Main perceived obstacles and barriers for the development, improvement and translation of RD research results for the period 2020/2021 vs 2023**

	<b>2020/21<sup>51</sup></b>	<b>2023</b>
<b>Language</b>	<b>17% (1 country)</b> Slovakia	-
<b>Funding</b>	<b>83% (5 countries)</b> Bulgaria, Czech Republic, Estonia, Lithuania, Poland Romania	<b>100% (7 countries)</b> Bulgaria, Czech Republic, Estonia, Lithuania, Poland, Romania, Slovakia
<b>Difficulties in accessing to national resources for funding research and development of RD projects</b>	<b>43% (3 countries)</b> Bulgaria, Lithuania, Romania	<b>71% (5 countries)</b> Bulgaria, Lithuania, Romania, Poland, Slovakia
<b>Lack of options</b>	<b>29% (2 countries)</b> Estonia, Lithuania	<b>14% (1 countries)</b> Romania

Finally, regarding the participation of the EU-13 Countries to EU/international RD projects, there have been improvements regarding the “Link to potential partners”, as well as on the “Information on funding opportunities”, and in the perception of “Irrelevance of programme topics and goals for the own research agenda”, that saw a decrease in four, two and one counties/country respectively.

On the other hand, there have been more countries indicating as obstacle to the participation in EU/international RD projects the “Bureaucratic application on responding procedures” and the “Quality of support of national contact points”, highlighted in 2023 respectively from two and one countries/country more than in 2020/21.

The results are summarised in Table 25.

**Table 25. Most important estimated obstacles and barriers for the participation in EU/International projects in the RD field for the period 2020/2021 vs 2023**

	<b>2020/21</b>	<b>2023</b>
<b>Lack of information on funding opportunities</b>	<b>67% (4 countries)</b> Estonia, Lithuania, Poland, Romania	<b>29% (2 countries)</b> Romania, Slovakia
<b>Limited links to potential partners</b>	<b>86% (6 countries)</b> Bulgaria, Czech Republic, Estonia, Lithuania, Romania, Slovakia	<b>29% (2 countries)</b> Bulgaria, Lithuania

<sup>51</sup> Most recent data from the surveys 2020/2021 provided by the country

<b>Bureaucratic application on responding procedures</b>	<b>57% (4 countries)</b> Bulgaria, Czech Republic, Estonia, Romania	<b>86% (6 countries)</b> Bulgaria, Czech Republic, Estonia, Romania, Poland, Slovakia
<b>Irrelevance of programme topics and goals to own research agenda</b>	<b>29% (2 country)</b> Lithuania, Poland	<b>14% (1 country)</b> Lithuania
<b>Quality of support provided by national contact points</b>	<b>29% (2 countries)</b> Czech Republic, Slovakia	<b>43% (3 countries)</b> Czech Republic, Romania, Poland



## Discussion

The discussion part of this last deliverable analysing the national state of play and alignment process with EJP RD will recall the results of the 2023 edition of the survey and will focus on the follow-up that can be drawn by comparing the outcomes obtained in the different editions of the survey.

### Edition 2023

The results obtained for all 25 countries participating to the 2023 edition of the survey will be shortly summarized to draw a status quo of the alignment status with the activities of the four EJP RD Pillars at M51:

- An overall good presence of NP/NS for RD, active or expired is in place, (88% of the countries), with 20% of the countries in the process of renewing the expired NP/NS for RD
- A general better alignment is observable towards the activities falling under Pillar 3 "Capacity building and empowerment", followed by the activities of Pillar 2 "Resources and services to foster research on RD", even if in a lower rate regarding the support to FAIR data
- The national undertakings revealing to be less promoted are those falling under the activities especially of Pillar 4 "Accelerated translation of research projects and improvement of outcomes of clinical studies", and then of Pillar 1 "National and International investments on research in the field of RD", although for these last a relative positive alignment is observable when considering the promotion of national calls for research projects.
- Regarding the EU-13 Countries, the most frequent reported obstacles and barriers for the development, improvement and translation of RD research results appear to be "Funding" (indicated by all responding EU-13 Countries), and "Difficulties in accessing to national resources for funding of research and development of RD projects". The most frequent emerged obstacles and barriers regarding the country's' participation in EU/international projects in the RD field have been instead the "Bureaucratic application on responding procedures", and the "Quality of support provided by national contact points".

### Follow-up analysis from the surveys 2020/21-2023

It must be highlighted that thirty-four of the thirty-six countries contacted through the years 2020, 2021 and 2023 submitted a complete survey, thus constituting a rather large sample of the targeted countries, and that 19 of these (56%) participated in 2023 and in at least one of the editions 2020/21. Furthermore, it has to be underlined that for 15 of these 19 countries (79%) the survey has been filled by the same reference person over time, and for other two countries by different persons, belonging to the same institution.

A good result has been obtained also for reaching all the EU-13 Countries in at least one edition of the survey, with seven of them allowing follow-up suggestions.

Of the 19 countries, a high number resulted having adopted a NP/NS for RD at some stage (84%), with an increase of 5% in respect to the period 2020/21. Noteworthy one country that in 2020/2021 declared to have a NP/NS under development informs not to have a NP/NS for RD, neither active nor under development, indicating a possible decline in the progress that would deserve a more thorough investigation to understand the eventual reasons of this halt.

Six of the NP/NS for RD, or list of measures in two cases (42% totally), that in 2020/21 were expired appear to be currently renewed or under renewal, suggesting though that the drive towards these national RD actions has not stopped.

With respect to the alignment status with the four EJP RD Pillars the following considerations can be highlighted:

Alignment with Pillar 1 “National and International investments on research in the field of RD”:

**Key point: investments to share knowledge require particular attention, especially in EU-13 Countries, and overall, further efforts are advisable to maintain and improve the positive results observed in the promotion of national and transnational calls for research projects.**

From the comparison of the results, it appears that for Pillar 1 the support towards investments to share knowledge on RD continues to be the aspect on RD research needing most to be supported by the NP/NS for RD. Twelve (46%) of the 19 countries are in fact not endorsing this initiative in their plans and strategies. Among these twelve, ten never started and two stopped the support in this area. The networking Support Scheme of WP7 of the EJP RD should be in this perspective further disseminated as tool to address RD knowledge-sharing between countries for the rest of the duration of the project.

National and transnational calls for research projects feature among the activities of Pillar 1 that receive more attention from the NP/NS for RD (respectively in 58% and 53% of the cases), and a positive trend has been observed with an increase for both. Nevertheless, some efforts should address the reinforcement of actions in this field, especially for the transnational calls, given the significant importance of research on RD.

For the EU-13 countries a certain positive run emerges for both the promotion of national and transnational calls for research projects by the NP/NS for RD, with an enhancement of 43% for the national and of 29% for the transnational calls, although the topic of the promotion of calls for RD research projects remains still a challenge as more than 40% of the countries remain in an unvaried lack of such national and transnational initiatives. Also, for this target of countries, the need to concentrate efforts dedicated to investments to share knowledge is remarkable, as 72% of the countries declare a lack in this field, resulting in 14% as a loss, and in 58% as the persisting of absence.

Looking at the support of other public or private funding initiatives for research/networking in the field of RD, the situation appears even more in need of targeted intervention in the 19 countries: 42% of the countries declared a negative variation, that adds to 32% of countries in an unvaried absence for the other public initiatives, while 47% showed a continuation of shortage of private funding initiatives, with four more countries no longer supporting them. These results could nevertheless suggest that overall, more attention has been given to support to RD research through the NP/NS for RD, in respect to what was observed via the previous data collections of these series and could invite the EJP RD to further increase the dialogue with the national/regional stakeholders to counterbalance possible inequalities

between countries. Another statement could be the necessity to foster specific RD research efforts, as broader but not RD targeted health research policies could be not sufficient to address RD research requirements.

In general, dissemination and information activities on existing EU funding opportunities could be pursued to trigger the awareness and potential in national policy makers on such opportunities. Efforts are moreover needed to further assess specific bottlenecks on funding procedures.

Alignment with Pillar 2 “Resources and services to foster research on RD”:

**Key points: an encouraging alignment with the activities of Pillar 2 emerges with respect to the NP/NS for RD, especially for the EU- 13 Countries, whereas such positive picture does not emerge for the other activities. A special effort is needed to further enhance the support to FAIR data by the NP/NS for RD and towards the other initiatives on all topics of this Pillar.**

More than 50% of the 19 countries appear to endorse data repositories and tools for research on RD through their NP/ND for RD (namely 58%). The topics mainly covered regarding the data repositories and tools, covered in 2023 by more than 50% of the NP/NS for RD are: “Registries catalogue”, “Data deposition and analysis”, “Ontologies and codification”, although a light decrease in the percentage of NP/NS for RD supporting these topics has been observed in respect to what was revealed in the previous surveys. Besides the observation that 58% of the NP/NS for RD are in a positive condition towards the support to data repositories and tools for research on RD, it shows up that 26% of the 19 countries went through the loss of this support, for a total of 31% of the NP/NS for RD not supporting data repositories and tools in 2023. This adverse trend is even accentuated when considering other public and private funding initiatives for the support to data repositories and tools, as 74% indicate the loss/continued absence of other public initiatives and 73% of private funding initiatives.

Focusing on the EU-13 Countries only 14% of the countries faced a negative variation in the support provided by the NP/NS for RD to data repositories and tools for research on RD. Conversely, the NP/NS for RD of the remaining 86% of the countries figure either in the condition of continuing the support (43%) or of having started to undertake it (43%). On the opposite, when investigating the support to data repositories and tools endorsed by other public or private initiatives, these appear to be continuously unavailable or left behind in 86% of the countries.

Moving to the support to FAIR data of the NP/NS for RD an encouraging increase has been recorded in 26% of the countries, with globally 37% of the NP/NS for RD supporting FAIR data in 2023. This enhancement lowered the percentage of NP/NS for RD not supporting FAIR data from 74% to 53% in the 19 countries in 2023. Less achievements can be reported on this topic referring to other initiatives than the NP/NS for RD, as an unvaried negative position has been detected for 52% of the countries, in addition to 26% of the countries facing the loss of support. On the other hand, the NP/NS for RD of the EU-13 Countries support FAIR data in 57% of the cases. This result is even more promising, considering that all 7 EU-13 Countries did not support FAIR data through the NP/NS for RD in the period 2020/2021, whereas 4 countries show up to have engaged in this support in the last data collection. This enhancement is centred on the NP/NS for RD, as for the other initiatives the condition towards the support

to FAIR data remains rather unvaried, with 72% of the countries persisting in the lack of support and 14% losing it.

Multidisciplinary holistic approaches for RD keep receiving a high support from the NP/NS for RD (79% of the cases, globally), while other initiatives seem not to be diffused for this kind of efforts (absent in 53% or dismissed in 21% of the countries respectively). For this topic, too, the situation appears more favourable for the NP/NS for RD of the EU-13 Countries, as only 14% of the NP/NS for RD do not adopt such approaches. With regard to the other initiatives that support multidisciplinary holistic approaches for RD, there appears a general need of dedicated attention.

To face the emerged challenges of Pillar 2 the following broad indications can be reaffirmed: continue to progress in the effort of promoting FAIR data, especially through the NP/NS for RD, and in the effort of making connections between RD dedicated projects for the support to data repositories and tools for RD research. Also, the involvement in RD projects of multistakeholder bodies, such as NMGs, could encourage addressing the challenges set by the multidisciplinary holistic approaches.

#### Alignment with Pillar 3 “Capacity building and empowerment”

**Key points: More attention to RD trainings promoted by other activities than the NP/NS for RD should be given.**

The support to training activities continues to receive particular relevance in the NP/NS for RD, with even more countries endorsing these kind of actions in 2023 (80% of NP/NS for RD endorsing training activities in 2023 vs 68% in 2020/2021).

Less relief is given to RD trainings when looking at other initiatives than the NP/NS for RD, where it emerges that there has been even a lowering of 32% in the number of countries promoting such initiatives. This lowering, added to the countries that did not support other initiatives for RD trainings than those promoted by the NP/NS for RD in 2020/2021, results in a total of 69% of the countries missing these activities in 2023.

The NP/NS for RD of the 7 EU-13 Countries disclose to promote in 100% of the cases RD trainings. More in detail, two of the countries that had not started such activities in 2020/21 appear to have introduced them in 2023. On the other hand, as already described for the general sample, other activities lack in supporting RD trainings, globally in 72% of the EU-13 Countries. Among these, two countries (29%) inform to have dismissed other initiatives dedicated to RD trainings.

To tackle the needs emerged in the field of RD trainings specific training topics should be addressed through the NP/NS for RD (such as FAIR data or Biobanks and Data Quality trainings). Both online as well as in-site trainings should be developed and spread, with dedicated funds for awarding of fellowships, if needed.

#### Alignment with Pillar 4 “Accelerated translation of research projects and improvement of outcomes of clinical studies”

**Key points: the rapid translation of research results in clinical studies and healthcare and the development of innovative methodologies tailored for clinical trials require high attention to be improved in the NP/NS for RD and in other initiatives, especially considering EU-13 Countries**

In continuity with what has been observed in the previous editions of the survey, a certain positive alignment of the NP/NS for RD towards the rapid translation of research results in clinical studies and healthcare arises also in 2023 (21% already endorsed these initiatives in 2020/21 and another 21% joining these efforts in 2023). Nevertheless, the rapid translation of research results in clinical studies and healthcare needs to be still reinforced in 48% of the 19 countries.

This need is even more pronounced regarding other initiatives than the NP/NS for RD, where 73% of the countries continue not to promote the rapid translation and 11% stopped doing so.

High attention should be given to the development of innovative methodologies tailored for clinical trials, for which 73% of the NP/NS for RD do not foresee a support. The above considerations can be applied also when looking at the EU-13 Countries. In all, 72% of the NP/NS for RD resulted not having undertaken/having stopped the promotion of a rapid translation of research results in clinical studies and healthcare, and 86% not having undertaken/having stopped the promotion of the development of innovative methodologies tailored for clinical trials. On the same line, for the other initiatives than the NP/NS for RD, for which 100% of the seven EU-13 Countries show to be still in the lack of these initiatives.

To meet the needs emerged for Pillar 4, recurrent possibilities of exchanges between RD research related experts should be encouraged and implemented, as well as the wider diffusion of the already existing innovative methodologies tailored for clinical trials.

#### EU-13 Countries' status of NP/NS for RD and specific needs, obstacles and advancements

All 7 EU-13 Countries participating to the survey in 2020/21 and 2023 adopted a NP/NS for RD at some stage. At the time of the last data collection the NP/NS for RD of one country resulted having been approved but was not active, three countries were not renewing the expired NP/NS for RD, while for one further country the renewal had started, and for two countries the NP/NS for RD appeared to be in force. Coming to the main perceived obstacles and barriers for the development, improvement and translation of RD research results, an evolution in a positive sense has been observed towards the topic of "Language" and "Lack of options for exploitation of research results" (that saw both the decrease in 14% of the countries), whereas for the topic "Difficulties in accessing to national resources for funding research and development of RD projects" an increase has been registered in 28% of the countries (with 71% countries indicating this as an issue in 2023). Besides this topic, still highly significant remains the data on "Funding", indicated as obstacle/barrier by 100% of the seven countries in 2023 (with an increase of 14% of the countries in respect to 2020/21).

Regarding the countries' participation in EU/international projects in the RD field, an enhancement has been detected in the areas of "Lack of information of funding opportunities", "Limited links to potential partners", no longer highlighted in 2023 by 38% of the countries, and "Irrelevance of programme topics to own research agenda", no longer pointed by 14% of the countries. Conversely, the topics "Bureaucratic application on responding procedures" has been identified as obstacle in

2023 by 86% of the countries (with an increase of 29% of the countries who indicated this area), together with "Quality of support provided by national contact points", stressed by 43% of the countries in 2023 (with an increase of 14% of the countries).

To face the main recurrent obstacles and barriers faced by the EU-13 Countries for the development, improvement and translation of RD research results, RD dedicated funding should be increased, facilitating also the access to funding for research and development of RD projects. On the other hand, the assistance for bureaucratic application on responding procedures and the quality of support provided by national contact points could be implemented to improve the participation in EU/international projects in the RD filed. All these initiatives addressed to specific EU-13 Countries perceived obstacles and barriers could be tackled by dedicated trainings, targeting among others also national policy makers and representatives of the Ministries of Health and Research.

## **Conclusions and next actions**

This fourth data collection allowed to reach six countries that did not participate to the previous editions of the survey, for a total of thirty-four countries who furnished data on the status of national and international RD undertakings and on their alignment with the activities promoted by the four EJP RD Pillars over the years 2020 to 2023. (94% of the contacted countries).

The data collected in 2023 are in line with the trend observed in the previous data collections, with a higher alignment of the national RD actions towards the activities of Pillar 3 of the EJP RD, followed by those of Pillar 2, whereas a lower accordance has been detected towards the activities of Pillar 4 and Pillar 1. Overall, the alignment emerges to be higher when considering the NP/NS for RD when compared to other national RD initiatives.

The follow-up comparisons performed for the countries that participated both in 2023 and in one or more of the editions 2020/2021 can suggest the specific areas of the four Pillars in which there have been the main achievements on the alignment status, as well as the areas that still need dedicated efforts at national and international level in the remaining months of the EJP RD, and that could be addressed by coming RD projects.

The areas in which the RD undertakings saw an increased alignment with the EJP RD activities over the period 2020-2023 have been:

- The promotion of national calls for research projects by the NP/NS for RD (Pillar 1)
- The promotion of transnational calls for research projects by the NP/NS for RD (Pillar 1)
- The promotion of FAIR data by the NP/NS for RD (Pillar 2)
- The promotion of the rapid translation of research results in clinical studies and healthcare by the NP/NS for RD (Pillar 4).

The positive results obtained in these areas should serve as basis to draw best-practices and hints to further advance in the specific topics.

On the other hand, the fields that demonstrated a persisting criticality in the alignment, or in some cases a loss in the support, have been:

- The promotion of investments to share knowledge, by the NP/NS for RD (Pillar 1)
- The existence of private funding initiatives for research/networking (Pillar 1)
- The adoption of multidisciplinary holistic approaches and the promotion of data repositories and tools for research on RD in respect to other initiatives than the NP/NS for RD
- The promotion of FAIR data by both the NP/NS for RD and by other initiatives, despite the relative positive trend for the FAIR data cited above for the NP/NS for RD (Pillar 2)
- The promotion of RD trainings by other initiatives than the NP/NS for RD (Pillar 3)
- The promotion of the rapid translation of research results in clinical studies and healthcare both the by NP/NS for RD and by other initiatives (despite the relative positive trend cited above regarding the NP/NS for RD), and the development of innovative methodologies tailored for clinical trials by the NP/NS for RD, (Pillar 4).

A specification must be made for the support to FAIR data, and for the promotion of the rapid translation of research results in clinical studies and healthcare, that result to be at the same time among the areas showing greater improvements, especially when considering the NP/NS for RD, and areas most frequently appearing among the still open challenges. The fruitful efforts unfolded for the promotion of FAIR data and for the rapid translation of research results in clinical studies and healthcare that led to an improvement in these fields should be therefore further exploited and strengthened to keep improving in these crucial areas.

In addition, it can be stated that the alignment with the activities of Pillar 3 kept the highest alignment state over the years, although a remarkable decrease has been observed when looking at other initiatives than the NP/NS for RD for this Pillar.

The indication on whether the enhancements or still open challenges refer to the NP/NS for RD or to other initiatives should be considered by the national policy makers and experts involved at all level in RD undertakings for more targeted interventions.

Overall, these outcomes appear to be encouraging, as the major improvements have been registered in Pillar 1 and at some degree in Pillar 4, that in all the data collections over the period 2020 to 2023 appeared to be the most critical areas. The same positive statement can be made for the crucial RD activity represented by the promotion of FAIR data, that constituted a specific open challenge for Pillar 2 over the years.

Also, in respect to the main obstacles and barriers expressed by the EU-13 Countries encouraging advancements have been registered both in relation to the development, improvement and translation of RD research results, and to the participation in EU/International projects in the RD field.

The results of these analysis have been presented at the occasion of the Second Strategic Workshop with national policy makers, held on 5 July 2023 in Brussels as a hybrid event.

The results will be moreover handed to Pillar Leader as feedback on the work done in the timeframe January 2019-March 2023, and as hints for future RD initiatives, also beyond the EJP RD.





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<b>COVID-19</b>	<b>Corona Virus Disease-19</b>
<b>D</b>	<b>Deliverable</b>
<b>ERN(s)</b>	<b>European Reference Network(s)</b>
<b>EJP RD</b>	<b>European Joint Programme on Rare Diseases</b>
<b>EU</b>	<b>European Union</b>
<b>FAIR</b>	<b>Findable, Accessible, Interoperable, Reusable</b>
<b>GDPR</b>	<b>General Data Protection Regulation</b>
<b>INSERM</b>	<b>Institut National de la Santé et de la Recherche Médicale</b>
<b>IRDiRC</b>	<b>International Rare Diseases Research Consortium</b>
<b>M</b>	<b>Month</b>
<b>MS</b>	<b>Member States</b>
<b>NMG(s)</b>	<b>National Mirror Group(s)</b>

<b>NP</b>	<b>National Plan(s)</b>
<b>NS</b>	<b>National Strategy(ies)</b>
<b>R&amp;I</b>	<b>Research and Innovation</b>
<b>RD</b>	<b>Rare Disease(s)</b>
<b>T</b>	<b>Task</b>
<b>WP</b>	<b>Work Package</b>

## Annex 1 Survey "National Plans and Strategies for Rare Diseases", edition 2023

### **National Plans and Strategies for Rare Diseases Edition 2023**

This survey aims at collecting information from EU Member States on the state of the art regarding the development and implementation of National Plans and Strategies for rare diseases and on the alignment process with the European Joint Programme on Rare Diseases, EJP RD, (GA 825575) relevant/complementary actions performed at national level, with a specific focus on EU- 13 Countries in respect to their specific needs, obstacles and advancements. Please fill in the survey by referring to the National Plan or Strategy for rare diseases in your Country. Be aware that some questions do not relate directly to the National Plan or Strategy for rare diseases but concern the rare disease field in a broader context.

#### GDPR

This survey form is specifically dedicated to collect information for the purpose of the European Joint Programme on Rare Diseases, EJP RD, WP 2 "Integrative Research and Innovation Strategy", "Task 2.5 "Translation/impact of prioritization on national and EU strategies". We collect Personal Data freely provided by the user including (but not limited to): name, email address, and any other details specifically asked in registration forms. EJP RD does not share personally identifiable information with unrelated Third Parties. However, we may disclose, transfer or share your Personal Data-anonymized or in its original format- with certain third parties without further notice to you, only for the purpose of the organization and follow up of this event. Information collected on this form will be held in compliance with the General Data Protection Regulation (EU Regulation 2016/679) (GDPR) of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. Data will be processed and stored for a maximum of 15 years. If you want to have more information on data processing, for example know how your personal data is being processed, or if you want to exercise your rights according to articles 15-22 of the GDPR, or if you notice a personal data breach according to Articles 33-34, please contact the data controller who determines the purposes and means of the processing of personal data. Contact details: [coordination@ejprarediseases.org](mailto:coordination@ejprarediseases.org) (mail to: [coordination@ejprarediseases.org](mailto:coordination@ejprarediseases.org))

1. I have read the above-mentioned information and (please note that the GDPR authorization is required to participate to the survey)
  - I authorize the processing of personal data, in compliance with the European General Data Protection Regulation, Reg (EU) 2016/679 for the specific purpose they are collected (any communication of personal data to private or public subject will be allowed only for the specific purpose they are collected)
  - I do not authorize the processing of personal data, in compliance with the European General Data Protection Regulation, Reg (EU) 2016/679 for the specific purpose they are collected (any communication of personal data to private or public subject will be allowed only for the specific purpose they are collected), **so I renounce participating to the survey**

2. I have read the above mentioned information and
  - I authorize to be contacted for involvement in future collaborative initiatives, which might fall within the scope of my research activity
  - I authorize to be contacted for dissemination and communication activities (e.g., newsletters, invitations to meetings)

**General information**

3. First Name

4. Last Name

5. Email address

6. Institution

7. Is there an approved National Plan/Strategy for rare diseases (NP/NS for RD) in your Country?

- Yes, the NP/NS for RD of my country has been approved and is in force
- Yes, but the approved NP/NS for RD is not active
- Yes, the NP/NS for RD of my country expired, and a renewed version is under development
- Yes, but the NP/NS for RD of my country expired and is not under renewal
- A NP/NS for RD has been developed and is under approval in my country
- No, but a NP/NS for RD it is under development in my country
- No
- I don't know

8. Please describe the main obstacles to the renewal of the expired NP/NS for RD of your country

9. Please specify when the NP/NS for RD expired

10. Please provide the link to the NP/NS for RD of your country (active or expired)

11. When was the NP/NS for RD approved in your country? Please specify year

12. Is there a periodical evaluation of the NP/NS for RD in your country?

- Yes
- No
- I don't know

13. How many editions of the NP/NS for RD has your country adopted by now?

14. Are you directly involved in the implementation or development of the NP/NS for RD of your country?

- Yes
- No

15. If not, could you kindly provide a contact of a person who is directly involved in the NP/NS for RD of your country?

- Yes
- No

16. Please provide the name of the person who is directly involved in the NP/NS for RD of your country

17. Please provide the email address of the person who is directly involved in the NP/NS for RD of your country

18. Does the NP/NS for RD of your country promote national calls for research projects?

*National and International Investments in the field of RD*

- Yes
- No
- I don't know

19. If yes, please specify on which topic

20. Does the NP/NS for RD of your country promote transnational calls for research projects?

- Yes
- No
- I don't know

21. If yes, please specify on which topic

22. Does the NP/NS for RD of your country foresee investments to share knowledge?

- Yes
- No
- I don't know

23. If yes, please specify on which topic

24. Does the NP/NS for RD of your country support data repositories and tools for research on RD?

*Resources and Services to foster research on RD*

- No
- I don't know
- Yes, the NP/NS for RD promotes the development of data repositories and tools for RD research
- Yes, the NP/NS for RD promotes the implementation of data repositories and tools for RD research
- Yes, the NP/NS for RD promotes both the development and implementation of data repositories and tools for RD research

25. If the NP/NS for RD of your country supports data repositories and tools for research on RD, please specify the topic (possible multiple choice)

- Registries catalogue
- Biobanks catalogue
- Ontologies and codification
- OMIC services
- Cell lines
- Animal models
- Semantic Standards
- Support for clinical/translational research
- Access & privacy control
- Data deposition & analysis
- Tools
- Other

26. Does the NP/NS for RD of your country support FAIR\* data? (Findable, Accessible, Interoperable, Reusable)

- Yes
- No
- I don't know

27. If yes, please specify how the NP/NS for RD of your country supports FAIR data

28. Does the NP/NS for RD promote the adoption of multidisciplinary/holistic approaches for RD?

- Yes
- No
- I don't know

29. If yes, please specify on which topic

30. Does the NP/NS for RD of your country promote training activities for RD?  
*Capacity building and empowerment*

- Yes
- No
- I don't know

31. If yes, on which topics? (Possible multiple choice)

- Data management
- Data quality
- FAIR data
- Standards and quality of genetics/genomics data in clinical practice and laboratories
- Registries
- Biobanks
- Empowerment of the patients
- Online education courses
- Other

32. Does the NP/NS for RD of your country promote a rapid translation of research results in clinical studies and healthcare?

*Accelerated translation of research projects and improvement of clinical studies and healthcare*

- Yes
- No
- I don't know

33. If yes, please specify on which topic

34. Does the NP/NS for RD of your Country promote the development of innovative methodologies tailored for clinical trials?

- Yes
- No
- I don't know

35. If yes, please specify on which topic

36. Are there other relevant initiatives for RD in your country, than the NP/NS?

- Yes
- No
- I don't know

37. Are you directly involved in other initiatives for RD in your country, other than the NP/NS?

- Yes
- No

38. If yes, please specify on which topic



39. Please describe the topics of the RD initiatives, other than the NP/NS for RD, and any involvement you may have

40. Are there other public funding initiatives that promote national calls for research/networking in the field of RD in your country, apart from the NP/NS for RD?

- Yes
- No
- I don't know

41. If yes, please specify on which topic

42. Are there private funding initiatives for national calls for research/networking in the field of RD in your country?

- Yes
- No
- I don't know

43. If yes, please specify on which topic

44. Are there other public funding initiatives that promote transnational calls for research/networking in the field of RD in your country, apart from the NP/NS for RD?

- Yes
- No
- I don't know

45. If yes, please specify on which topic

46. Are there private funding initiatives for transnational calls for research/networking in the field of RD in your country?

- Yes
- No
- I don't know

47. If yes, please specify on which topic

48. Are investments to share knowledge foreseen by other public national initiatives than the NP/NS for RDs?

- Yes
- No
- I don't know

49. If yes, please specify on which topic

50. Are investments to share knowledge foreseen by private national initiatives for RD?

- Yes
- No
- I don't know

51. If yes, please specify on which topic

52. Is there an advisory body of national experts for Research and Innovation in your country? (Possible multiple choice)

- Yes, and advisory exists, but not specific for RD
- Yes, an advisory body exists, specific for RD
- No
- I don't know

53. Are there other public initiatives, than the NP/NS for RD of your country, that support data repositories and tools for research on RD?

- Yes, other public initiatives promote the development of data repositories and tools for RD research
- Yes, other public initiatives promote the implementation of data repositories and tools for RD research
- Yes, other public initiatives support both the development and implementation of data repositories and tools for RD research
- No
- I don't know

54. If yes, please specify on which topic (Possible multiple choice)

- Registries catalogue
- Biobanks catalogue
- Ontologies and codification
- OMIC services
- Cell lines
- Animal models
- Semantic standards
- Support for clinical/translational research
- Access & privacy control
- Data deposition and analysis
- Tools
- Other

55. Are there other private initiatives in your country, than the NP/NS, that support data repositories and tools for research on RD?

- Yes, other private initiatives promote the development of data repositories and tools for RD research

- Yes, other private initiatives promote the implementation of data repositories and tools for RD research
- Yes, other private initiatives support both the development and implementation of data repositories and tools for RD research
- No
- I don't know

56. If yes, please specify on which topic (Possible multiple choice)

- Registries catalogue
- Biobanks catalogue
- Ontologies and codification
- OMIC services
- Cell lines
- Animal models
- Semantic standards
- Support for clinical/translational research
- Access & privacy control
- Data deposition and analysis
- Tools
- Other

57. Are there other national initiatives for RD, than the NP/NS, that support FAIR\* data? (\*Findable, Accessible, Interoperable, Reusable)

- Yes
- No
- I don't know

58. If yes, please specify how FAIR data are supported by other initiatives than the NP/NS for RD

59. Are there other national initiatives, than the NP/NS, that promote the adoption of multidisciplinary approaches for RD?

- Yes
- No
- I don't know

60. If yes, please specify on which topic

61. Are there other initiatives, than the NP/NS, that support training activities for RD?

- Yes
- No
- I don't know

62. If yes, please specify on which topic (possible multiple choice)

- Data management
- Data quality
- FAIR data
- Standards and quality of genetics/genomics data in clinical practice and laboratories
- Registries
- Biobanks
- Empowerment of the patients
- Online education courses
- Other

63. Please briefly describe the training activities that are supported by other initiatives than the NP/NS for RD

64. Are there other initiatives, than the NP/NS, that promote a rapid translation of research results in clinical studies and healthcare?

- Yes
- No
- I don't know

65. If yes, please specify on which topic

66. Are there other initiatives, than the NP/NS, that promote the development of innovative methodologies tailored for clinical trials?

- Yes
- No
- I don't know

67. If yes, please specify on which topic

68. Did the EJP RD activities promote, trigger, or help to enforce RD undertakings that were not implemented or deemed so far in your country?

- Yes
- No

69. If yes, please specify on which topic (Possible multiple choice)

- Increased participation in national calls for research projects
- Increased participation in transnational calls for research projects
- Support to the implementation of FAIR data
- Promotion of rapid translation of research results into clinical studies and healthcare

- Promotion of the development of innovative methodologies tailored for clinical trials
- No

70. Did the EJP RD activities promote, trigger, or help the establishment and/or implementation of data repositories and tools for research in RD?

- Yes
- No

71. If yes, please specify on which topic (possible multiple choice)

- Registries catalogue
- Biobanks catalogue
- Ontologies and codification
- OMIC services
- Cell lines
- Animal models
- Semantic standards
- Support for clinical/translational research
- Access & privacy control
- Data deposition and analysis
- Tools
- No

72. Did the EJP RD activities promote, trigger, or help the establishment of RD training activities?

- Yes
- No

73. If yes, please specify on which topic (possible multiple choice)

- The EJP RD activities did not promote, trigger, or help the establishment of RD training activities
- Data management
- Data quality
- FAIR data
- Standards and quality of genetics/genomics data in clinical practice and laboratories
- Registries
- Biobanks
- Empowerment of the patients
- Online education courses
- No

74. Which Country do you represent?

- Armenia
- Austria
- Belgium
- Bulgaria

- Canada
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Georgia
- Germany
- Greece
- Hungary
- Ireland
- Israel
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Serbia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- UK

75. Please describe briefly the reasons for not participating to the previous editions of this survey (editions 2020 and 2021)

76. What have been the most significant changes in the RD area in your country since 2019?

77. Based on your experience, what are the main obstacles and barriers in your country for the development, improvement and translation of RD research results?  
(Possible multiple choice)

- Language
- Funding

- Difficulties in accessing to national resources for funding research and development of RD projects
- Lack of options

78. Regarding your participation in EU/International projects in the RD field, what do you estimate to be the most important/obstacles and barriers? (Possible multiple choice)

- Limited links on drafting proposals
- Lack of information on funding opportunities
- Limited links to potential partners
- Bureaucratic application on responding procedures
- Irrelevance of programme topics and goals to own research agenda
- Quality of support provided by national contact points

79. Do you want to highlight any other aspect regarding the national policies and initiatives for RD of your country that were not included in the present survey? This question will end the survey (you will only be asked to specify, if you answer yes to this question)

- Yes
- No

80. If yes, please specify

End of module

## Annex 2 Links to the National Plans and Strategies for rare diseases

Armenia	-
Austria	<a href="https://www.sozialministerium.at/Themen/Gesundheit/Seltene-Krankheiten.html">https://www.sozialministerium.at/Themen/Gesundheit/Seltene-Krankheiten.html</a>
Bulgaria	<a href="https://www.mh.government.bg/media/filer_public/2015/04/17/programa-redki-bolesti-2009-2013.pdf">https://www.mh.government.bg/media/filer_public/2015/04/17/programa-redki-bolesti-2009-2013.pdf</a>
Cyprus	<a href="https://www.moh.gov.cy/Moh/MOH.nsf/All/CD61A07312284C0A422579DC0023AF8A/\$file/Strategic%20Plan%20Rare%20Diseases.pdf">https://www.moh.gov.cy/Moh/MOH.nsf/All/CD61A07312284C0A422579DC0023AF8A/\$file/Strategic%20Plan%20Rare%20Diseases.pdf</a>
Czech Republic non lo mette in questa edizione, si nelle vecchie-mettere?	<a href="http://www.mzcr.cz/dokumenty/narodni-akcni-plan-pro-vzacna-onemocneni-na-leta-2012-2014_6713_1.html">http://www.mzcr.cz/dokumenty/narodni-akcni-plan-pro-vzacna-onemocneni-na-leta-2012-2014_6713_1.html</a>  <a href="https://www.databaze-strategie.cz/cz/mzd/strategie/narodni-akcni-plan-pro-vzacna-onemocneni-na-leta-2015-2017">https://www.databaze-strategie.cz/cz/mzd/strategie/narodni-akcni-plan-pro-vzacna-onemocneni-na-leta-2015-2017</a>  <a href="https://www.databaze-strategie.cz/cz/mzd/strategie/narodni-akcni-plan-pro-vzacna-onemocneni-na-leta-2018-2020">https://www.databaze-strategie.cz/cz/mzd/strategie/narodni-akcni-plan-pro-vzacna-onemocneni-na-leta-2018-2020</a>  <a href="https://www.databaze-strategie.cz/cz/mzd/strategie/narodni-strategie-pro-vzacna-onemocneni-na-leta-2010-2020">https://www.databaze-strategie.cz/cz/mzd/strategie/narodni-strategie-pro-vzacna-onemocneni-na-leta-2010-2020</a>
Denmark	<a href="https://www.sst.dk/-/media/Udgivelser/2018/National-strategi-for-sj%C3%A6ldne-sygdomme.ashx?la=da&amp;hash=B5A18FDA9342BD25518110A67C42F8D645B2D572">https://www.sst.dk/-/media/Udgivelser/2018/National-strategi-for-sj%C3%A6ldne-sygdomme.ashx?la=da&amp;hash=B5A18FDA9342BD25518110A67C42F8D645B2D572</a>
Estonia	<a href="http://download2.eurordis.org/rdpolicy/National%20Plans/Estonia/Estonia_RD%20National%20Development%20Plan_2014_Estonia_n.pdf">http://download2.eurordis.org/rdpolicy/National%20Plans/Estonia/Estonia_RD%20National%20Development%20Plan_2014_Estonia_n.pdf</a>
France	<a href="https://sante.gouv.fr/IMG/pdf/pnmr_3_v25-09pdf.pdf">https://sante.gouv.fr/IMG/pdf/pnmr_3_v25-09pdf.pdf</a>
Georgia	<a href="https://www.mh.government.bg/media/filer_public/2015/04/17/programa-redki-bolesti-2009-2013.pdf">https://www.mh.government.bg/media/filer_public/2015/04/17/programa-redki-bolesti-2009-2013.pdf</a>
Germany	<a href="http://www.namse.de">www.namse.de</a>



Hungary	<a href="http://download2.eurordis.org/rdpolicy/National%20Plans/Hungary/2.Hungary_RD%20National%20Plan_2013-2020_English.pdf">http://download2.eurordis.org/rdpolicy/National%20Plans/Hungary/2.Hungary_RD%20National%20Plan_2013-2020_English.pdf</a>
Ireland	<a href="https://www.gov.ie/en/publication/7e05d-programme-for-government-our-shared-future/">https://www.gov.ie/en/publication/7e05d-programme-for-government-our-shared-future/</a>  <a href="https://assets.gov.ie/37342/da70fc6fadd24425b98311e679f4406b.pdf">https://assets.gov.ie/37342/da70fc6fadd24425b98311e679f4406b.pdf</a>  <a href="https://www.gov.ie/en/publication/a4ac1b-national-rare-disease-plan-for-ireland-2014-2018/">https://www.gov.ie/en/publication/a4ac1b-national-rare-disease-plan-for-ireland-2014-2018/</a>
Israel	-
Italy	<a href="http://www.salute.gov.it/imgs/C_17_pubblicazioni_2153_allegato.pdf">http://www.salute.gov.it/imgs/C_17_pubblicazioni_2153_allegato.pdf</a>
Latvia	<a href="https://likumi.lv/ta/id/294448-par-planu-reto-slimibu-joma-2017-2020-gadam">https://likumi.lv/ta/id/294448-par-planu-reto-slimibu-joma-2017-2020-gadam</a>
Lithuania	<a href="https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.435635">https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.435635</a>
Luxembourg	<a href="https://sante.public.lu/fr/publications/p/plan-national-maladies-rares-2018-2022.html">https://sante.public.lu/fr/publications/p/plan-national-maladies-rares-2018-2022.html</a>
Malta	-
Norway	<a href="https://www.regjeringen.no/no/dokumenter/nasjonale-strategi-for-sjeldne-diagnoser/id2867121/">https://www.regjeringen.no/no/dokumenter/nasjonale-strategi-for-sjeldne-diagnoser/id2867121/</a>
Poland	-
Portugal	<a href="https://dre.pt/dre/detalhe/despacho/2129-b-2015-66619921">https://dre.pt/dre/detalhe/despacho/2129-b-2015-66619921</a>  <a href="http://www.orpha.net/national/data/PT-PT/www/uploads/Plano-anual-2018.pdf">http://www.orpha.net/national/data/PT-PT/www/uploads/Plano-anual-2018.pdf</a>
Romania	<a href="http://bolirareromania.ro/sites/default/files/politici/DRAFT%20PNBR%2020210226.pdf">http://bolirareromania.ro/sites/default/files/politici/DRAFT%20PNBR%2020210226.pdf</a> (only in Romanian)
Serbia	<a href="https://www.zdravlje.gov.rs/tekst/351960/program-za-retke-bolesti.php">https://www.zdravlje.gov.rs/tekst/351960/program-za-retke-bolesti.php</a>
Slovakia	<a href="https://rokovania.gov.sk/RVL/Material/25963/1">https://rokovania.gov.sk/RVL/Material/25963/1</a> , plain text in Slovak here <a href="https://sazch.sk/narodny-program-zdravotnej-starostlivosti-o-pacientov-so-zriedkavymi-chorobami-do-roku-2030/?fbclid=IwAR1q_X-w-HhEGgMxzfY-EMYz22pXAKJ6Tv8745N6nTmLSU0J4sbmtxWRp0">https://sazch.sk/narodny-program-zdravotnej-starostlivosti-o-pacientov-so-zriedkavymi-chorobami-do-roku-2030/?fbclid=IwAR1q_X-w-HhEGgMxzfY-EMYz22pXAKJ6Tv8745N6nTmLSU0J4sbmtxWRp0</a>

Slovenia	<a href="https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.gov.si%2Fassets%2Fministrstva%2FMZ%2FDOKUMENTI%2FZDRAVJE%2Fobvladovanje-nenalezljivih-bolezni%2FNacrt-dela-na-podrocju-redkih-bolezni-v-Republiki-Sloveniji-2021-2030.docx&amp;wdOrigin=BROWSELINK">https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.gov.si%2Fassets%2Fministrstva%2FMZ%2FDOKUMENTI%2FZDRAVJE%2Fobvladovanje-nenalezljivih-bolezni%2FNacrt-dela-na-podrocju-redkih-bolezni-v-Republiki-Sloveniji-2021-2030.docx&amp;wdOrigin=BROWSELINK</a>
Spain	There are no updates
Switzerland	<a href="https://www.bag.admin.ch/bag/en/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/nationales-konzept-seltene-krankheiten.html">https://www.bag.admin.ch/bag/en/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/nationales-konzept-seltene-krankheiten.html</a>
The Netherlands	<a href="https://www.zonmw.nl/fileadmin/zonmw/documenten/Kwaliteit_van_zorg/NPZZ/NPZeldzame_Ziekten.pdf">https://www.zonmw.nl/fileadmin/zonmw/documenten/Kwaliteit_van_zorg/NPZZ/NPZeldzame_Ziekten.pdf</a>
UK	<a href="https://www.gov.uk/government/publications/rare-diseases-strategy">https://www.gov.uk/government/publications/rare-diseases-strategy</a>

Annex 3 Replies from all countries participating in the survey in 2020, in 2021 and in 2023

**Is there an approved NP/NS for RD in your country?<sup>52</sup>**

	2020	2021	2023
<b>Yes (active, expired, under renewal)</b>	<b>76% (16 countries)</b> Bulgaria, Czech Republic, Estonia, France, Germany, Ireland, Italy, Lithuania, Luxembourg, Portugal, Romania, Serbia, Slovakia, Spain, The Netherlands, UK	<b>71% (20 countries)</b> Austria, Belgium, Bulgaria, Croatia, Czech Republic, Estonia, France, Germany, Ireland, Italy, Latvia, Lithuania, Luxembourg, Portugal, Romania, Serbia, Slovakia, Spain, The Netherlands, UK	<b>84% (21 Countries)</b> Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Italy, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Switzerland, The Netherlands
<b>No</b>	<b>5% (1 country)</b> Sweden	<b>4% (1 country)</b> Sweden	<b>4% (1 country)</b> Israel
<b>It is under approval/development</b>	<b>19% (4 countries)</b> Canada, Hungary, Israel, Turkey	<b>25% (countries)</b> Armenia, Canada, Georgia, Hungary, Israel, Poland, Turkey	<b>12% (3 countries)</b> Canada, Georgia, Malta
<b>I don't know</b>	-	-	-

**Alignment process of the NP/NS for RD with the EJP RD Pillars 1-4<sup>53</sup>**

**Does the NP/NS for RD of your country promote national calls for research projects?**

	2020	2021 (no data for Israel)	2023
<b>Yes</b>	<b>44% (7 countries)</b> France, Germany, Ireland, Luxembourg, Spain, The Netherlands, UK	<b>56% (14 countries)</b> Armenia, Croatia, France, Georgia, Germany, Ireland, Latvia, Luxembourg,	<b>58% (14 countries)</b> Canada, Cyprus, Czech Republic, France, Georgia, Germany, Lithuania,

<sup>52</sup> 21 Countries participated to the survey in 2020. For the year 2021 it has to be considered that, given the short laps of time passed between the 2020 and 2021 editions of the survey (6 months), the outcomes of 2021 summarise the results obtained in 2020 and 2021, so that the 27 countries considered in 2021 include also the countries that did not give updates in 2021, but for whom the data of 2020 have still been considered as valid. 25 Countries participated in 2023. The percentage incidence of the tables of this section is calculated taking into account the specificity of 2021, as described above

<sup>53</sup> Comparison of the results collected from the three editions; the percentages refer to the number of countries provided by a NP/NS for RD, active or expired for 2020, active, expired or under development/approval for 2021 and 2023.

The percentages of the alignment status of the NP/NS for RD with the four EJP RD Pillars refer to 16 countries for the period 2020; to 26 countries for 2021 and to 24 countries for 2023

		Portugal, Romania, Spain, The Netherlands, Turkey, UK	Luxembourg, Norway, Portugal, Romania, Slovakia, Slovenia, Spain
<b>No</b>	<b>44% (7 countries)</b> Bulgaria, Estonia, Italy, Lithuania, Portugal, Romania, Serbia	<b>36 % (9 countries)</b> Austria, Belgium, Bulgaria, Czech Republic, Estonia, Italy, Lithuania, Poland, Serbia	<b>38% (9 countries)</b> Austria, Bulgaria, Denmark, Estonia, Italy, Poland, Serbia, Switzerland, The Netherlands
<b>I don't know</b>	<b>12% (2 countries)</b> Czech Republic, Slovakia	<b>8% (2 countries)</b> Canada, Slovakia	<b>4% (1 country)</b> Malta

**Does the NP/NS for RD of your country promote transnational calls for research projects?**

	<b>2020</b>	<b>2021 (no data for Israel)</b>	<b>2023</b>
<b>Yes</b>	<b>56% (9 countries)</b> Czech Republic, France, Germany, Ireland, Luxembourg, Portugal, Spain, The Netherlands, UK	<b>48% (12 countries)</b> Armenia, Croatia, Czech Republic, France, Germany, Ireland, Luxembourg, Portugal, Romania, Spain, The Netherlands, UK	<b>46% (11 countries)</b> Canada, Cyprus, Czech Republic, Germany, Lithuania, Luxembourg, Norway, Portugal, Romania, Slovakia, Spain
<b>No</b>	<b>38% (6 countries)</b> Bulgaria, Estonia, Italy, Lithuania, Romania, Serbia	<b>40% (10 countries)</b> Austria, Belgium, Bulgaria, Estonia, Georgia, Italy, Lithuania, Poland, Serbia, Turkey	<b>46% (11 countries)</b> Austria, Bulgaria, Denmark, Estonia, Georgia, Italy, Poland, Serbia, Slovenia, Switzerland, The Netherlands
<b>I don't know</b>	<b>6% (1 country)</b> Slovakia	<b>12% (3 countries)</b> Canada, Latvia, Slovakia	<b>8% (2 countries)</b> France, Malta

**Does the NP/NS for RD of your country foresee investments to share knowledge?**

	<b>2020</b>	<b>2021 (no data for Israel)</b>	<b>2023</b>
<b>Yes</b>	<b>44% (7 countries)</b> Bulgaria, Ireland, Lithuania, Luxembourg, Spain, The Netherlands, UK	<b>44% (11 countries)</b> Armenia, Bulgaria, Croatia, Georgia, Ireland, Lithuania, Luxembourg, Spain, The Netherlands, Turkey, UK	<b>38% (9 countries)</b> Canada, Cyprus, Georgia, Lithuania, Luxembourg, Norway, Poland, Slovenia, Spain
<b>No</b>	<b>44% (7 countries)</b>	<b>28% (7 countries)</b>	<b>54% (13 countries)</b>

	Czech Republic, Estonia, Germany, Italy, Portugal, Romania, Serbia	Austria, Estonia, Germany, Italy, Poland, Portugal, Serbia	Austria, Bulgaria, Czech Republic, Denmark, Estonia, Germany, Italy, Portugal, Romania, Serbia, Slovakia, Switzerland, The Netherlands
<b>I don't know</b>	<b>12% (2 countries)</b> France, Slovakia	<b>28% (7 countries)</b> Belgium, Canada, Czech Republic, France, Latvia, Romania, Slovakia	<b>8% (2 countries)</b> France, Malta

**Pillar 2**

**Does the NP/NS for RD of your country support data repositories and tools for research on RD?**

	<b>2020</b>	<b>2021 (no data for Canada and Israel)</b>	<b>2023</b>
<b>Yes</b>	<b>81% (13 countries)</b> Czech Republic, France, Germany, Ireland, Italy, Lithuania, Luxembourg, Portugal, Romania, Serbia, Spain, The Netherlands, UK	<b>79% (19 countries)</b> Armenia, Austria, Belgium, Bulgaria, Croatia, Czech Republic, France, Georgia, Germany, Ireland, Italy, Lithuania, Luxembourg, Romania, Serbia, Spain, Turkey, UK, The Netherlands	<b>63% (15 countries)</b> Bulgaria, Canada, Estonia, France, Georgia, Germany, Italy, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, Spain, Switzerland
<b>No</b>	<b>13% (2 countries)</b> Bulgaria, Estonia	<b>13% (3 countries)</b> Estonia, Poland, Portugal	<b>33% (8 countries)</b> Austria, Cyprus, Denmark, Luxembourg, Norway, Portugal, Serbia, The Netherlands
<b>I don't know</b>	<b>6% (1 country)</b> Slovakia	<b>8% (2 countries)</b> Latvia, Slovakia	<b>4% (1 country)</b> Czech Republic

**If the NP/NS for RD of your country supports data repositories and tools for research on RD, please specify the topic (possible multiple choice)<sup>54</sup>**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Registries catalogue</b>	<b>69% (9 countries)</b> Czech Republic, France, Germany, Ireland, Italy, Lithu-	<b>89% (16 countries)</b> Armenia, Austria, Belgium, Bulgaria, Croatia, Czech	<b>87% (13 countries)</b> Bulgaria, France, Georgia, Germany, Italy, Li-

<sup>54</sup> Percentages referring to the countries that answered "Yes" to the previous question

	ania, Luxembourg, Romania, Serbia	Republic, France, Georgia, Germany, Ireland, Italy, Lithuania, Luxembourg, Romania, Serbia, Turkey	thuania, Malta, Poland, Romania, Slovakia, Slovenia, Spain, Switzerland
<b>Biobanks catalogue</b>	<b>54% (8 countries)</b> Czech Republic, France, Ireland, Italy, Portugal, The Netherlands, UK	<b>53% (10 countries)</b> Armenia, Belgium, Czech Republic, France, Georgia, Ireland, Italy, Lithuania, The Netherlands, Turkey	<b>47% (7 countries)</b> Canada, Georgia, Italy, Lithuania, Malta, Slovenia, Spain
<b>Ontologies and codification</b>	<b>54% (7 countries)</b> Czech Republic, France, Germany, Lithuania, Luxembourg, Spain, UK	<b>68% (13 countries)</b> Austria, Belgium, Croatia, Czech Republic, France, Georgia, Germany, Ireland, Italy, Lithuania, Luxembourg, Spain, UK	<b>47% (7 countries)</b> France, Georgia, Germany, Italy, Lithuania, Poland, Slovenia
<b>OMIC services</b>	<b>8% (1 country)</b> France	<b>5% (1 country)</b> France	<b>13% (2 countries)</b> Canada, Lithuania
<b>Cell lines</b>	<b>8% (1 country)</b> Italy	<b>5% (1 country)</b> Italy	<b>13% (2 countries)</b> Canada, Spain
<b>Animal models</b>	<b>8% (1 country)</b> Italy	<b>5% (1 country)</b> Italy	<b>7% (1 country)</b> Canada
<b>Semantic standards</b>	<b>8% (1 country)</b> France	<b>5% (1 country)</b> France	<b>7% (1 country)</b> Poland
<b>Support for clinical/translational research</b>	<b>54% (8 countries)</b> Czech Republic, France, Ireland, Italy, Portugal, The Netherlands, UK	<b>47% (9 countries)</b> Armenia, Czech Republic, France, Georgia, Ireland, Italy, Portugal, The Netherlands, UK	<b>47% (7 countries)</b> Canada, France, Georgia, Lithuania, Malta, Romania, Slovenia
<b>Access &amp; privacy control</b>	<b>15% (2 countries)</b> France, Lithuania	<b>21% (4 countries)</b> Bulgaria, France, Georgia, Lithuania	<b>13% (2 countries)</b> Canada, Lithuania
<b>Data deposition and analysis</b>	<b>39% (5 countries)</b> France, Ireland, Lithuania, Portugal, UK	<b>47% (9 countries)</b> Belgium, Bulgaria, France, Ireland, Italy, Lithuania, Portugal, Turkey, UK	<b>47% (7 countries)</b> Canada, Estonia, France, Germany, Italy, Lithuania, Poland
<b>Tools</b>	<b>23% (3 countries)</b> France, Lithuania, UK	<b>32% (6 countries)</b> Armenia, Bulgaria, France, Lithuania,	<b>27% (4 countries)</b> Canada, Georgia, Lithuania, Spain

		Turkey, UK	
<b>Other</b>	<b>8% (1 country)</b> Luxembourg	<b>11% (2 countries)</b> Belgium, Luxembourg	-

**Does the NP/NS for RD of your country support FAIR\* data? (Findable, Accessible, Interoperable, Reusable)**

	<b>2020</b>	<b>2021 (no data for Canada)</b>	<b>2023</b>
<b>Yes</b>	<b>31% (5 countries)</b> France, Germany, Ireland, Spain, UK	<b>20% (5 countries)</b> France, Germany, Ireland, Italy, UK	<b>38% (9 countries)</b> Canada, France, Germany, Italy, Lithuania, Poland, Romania, Slovakia, Slovenia
<b>No</b>	<b>50% (8 countries)</b> Bulgaria, Czech Republic, Italy, Lithuania, Luxembourg, Romania, Serbia, The Netherlands	<b>52% (13 countries)</b> Austria, Belgium, Bulgaria, Czech Republic, Georgia, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, The Netherlands, Turkey	<b>50% (12 countries)</b> Austria, Bulgaria, Cyprus, Denmark, Estonia, Georgia, Luxembourg, Norway, Portugal, Serbia, Switzerland, The Netherlands
<b>I don't know</b>	<b>19% (3 countries)</b> Estonia, Portugal, Slovakia	<b>28% (7 countries)</b> Armenia, Croatia, Estonia, Israel, Latvia, Slovakia, Spain	<b>12% (3 countries)</b> Czech Republic, Malta, Spain

**Does the NP/NS for RD promote the adoption of multidisciplinary/holistic approaches for RD?**

	<b>2020</b>	<b>2021 (no data for Canada and Israel)</b>	<b>2023</b>
<b>Yes</b>	<b>81% (13 countries)</b> Bulgaria, France, Germany, Ireland, Italy, Lithuania, Portugal, Romania, Spain, The Netherlands, Luxembourg, Serbia, UK	<b>88% (21 countries)</b> Armenia, Austria, Belgium, Bulgaria, Croatia, France, Georgia, Germany, Ireland, Italy, Latvia, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Spain, The Netherlands, Turkey, UK	<b>84% (20 countries)</b> Austria, Bulgaria, Canada, Cyprus, Denmark, Estonia, France, Georgia, Germany, Italy, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Switzerland
<b>No</b>	<b>13% (2 countries)</b> Czech Republic, Estonia	<b>8% (2 countries)</b> Czech Republic, Estonia	<b>12% (3 countries)</b> Czech Republic, Norway, The Netherlands

I don't know	<b>6% (1 country)</b> Slovakia	<b>4% (1 country)</b> Slovakia	<b>4% (1 country)</b> Malta
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**Does the NP/NS for RD of your country promote training activities for RD?**

	2020	2021 (no data for Canada and Israel)	2023
<b>Yes</b>	<b>75% (12 countries)</b> Bulgaria, Czech Republic, France, Germany, Ireland, Lithuania, Luxembourg, Portugal, Romania, Serbia, Spain, UK	<b>75% (18 countries)</b> Armenia, Bulgaria, Croatia Czech Republic, France, Georgia, Germany, Ireland, Italy, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Spain, Turkey, UK	<b>84% (20 countries)</b> Austria, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, France, Georgia, Germany, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain
<b>No</b>	<b>19% (3 countries)</b> Italy, Estonia, The Netherlands	<b>17% (4 countries)</b> Belgium, Estonia, Latvia, The Netherlands	<b>12% (3 countries)</b> Norway, Switzerland, The Netherlands
<b>I don't know</b>	<b>6% (1 country)</b> Slovakia	<b>8% (2 countries)</b> Austria, Slovakia	<b>4% (1 country)</b> Italy

**If yes, on which topics? (Possible multiple choice)<sup>55</sup>**

	2020	2021	2023
<b>Data management</b>	<b>33% (4 countries)</b> Bulgaria, France, Ireland, Lithuania	<b>44% (8 countries)</b> Armenia, Bulgaria, Czech Republic, France, Georgia, Ireland, Lithuania, Turkey	<b>25% (5 countries)</b> Canada, Georgia, Lithuania, Malta, Poland
<b>Data quality</b>	<b>17% (2 countries)</b> Bulgaria, Lithuania	<b>22% (4 countries)</b> Armenia, Bulgaria, Georgia, Lithuania	<b>25% (5 countries)</b> Canada, Czech Republic, Georgia, Malta, Poland
<b>FAIR data</b>	-	<b>11% (2 countries)</b> Italy, Turkey	<b>10% (2 countries)</b> Canada, Poland
<b>Standards and quality of genetics/genomics data in clinical practice and laboratories</b>	<b>33% (4 countries)</b> Bulgaria, Czech Republic, Lithuania, Romania	<b>39% (7 countries)</b> Armenia, Bulgaria, Czech Republic, Lithuania, Poland, Romania, Turkey	<b>35% (7 countries)</b> Canada, Czech Republic, Denmark, Georgia, Lithuania, Poland,

<sup>55</sup> Percentages referring to the countries answering "Yes" to the previous question



			Portugal
<b>Registries</b>	<b>42% (5 countries)</b> Bulgaria, Czech Republic, France, Ireland, Lithuania	<b>61% (11 countries)</b> Bulgaria, Croatia, Czech Republic, France, Georgia, Ireland, Italy, Lithuania, Luxembourg, Poland, Romania	<b>45% (9 countries)</b> Bulgaria, France, Georgia, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia
<b>Biobanks</b>	<b>17% (2 countries)</b> Ireland, Lithuania	<b>28% (5 countries)</b> Armenia, Ireland, Lithuania, Poland, Turkey	<b>15% (3 countries)</b> Georgia, Germany, Poland
<b>Empowerment of the patients</b>	<b>83% (10 countries)</b> Bulgaria, Czech Republic, France, Ireland, Lithuania, Luxembourg, Portugal, Romania, Serbia, Spain	<b>72% (13 countries)</b> Bulgaria, Croatia, Czech Republic, France, Georgia, Ireland, Lithuania, Luxembourg, Poland, Portugal, Romania, Serbia, Spain	<b>70% (14 countries)</b> Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Georgia, Luxembourg, Poland, Portugal, Romania, Slovakia, Slovenia, Spain
<b>Online education courses</b>	<b>42% (5 countries)</b> Czech Republic, Ireland, Lithuania, Portugal, Romania	<b>39% (7 countries)</b> Czech Republic, Ireland, Georgia, Lithuania, Poland, Portugal, Romania	<b>45% (9 countries)</b> Bulgaria, Cyprus, Czech Republic, Denmark, Georgia, Poland, Portugal, Romania, Spain
<b>Other</b>	<b>25% (3 countries)</b> Lithuania, UK, Germany	<b>17% (2 countries)</b> Lithuania, UK, Germany	<b>20% (4 countries)</b> Austria, Estonia, Germany, Serbia

#### Pillar 4

#### Does the NP/NS for RD of your country promote a rapid translation of research results in clinical studies and healthcare?

	2020	2021 (no data for Canada and Israel)	2023
<b>Yes</b>	<b>38% (6 countries)</b> France, Ireland, Romania, Spain, The Netherlands, UK	<b>45% (11 countries)</b> Croatia, Czech Republic, France, Georgia, Ireland, Italy, Romania, Spain, The Netherlands, Turkey, UK	<b>38% (9 countries)</b> Canada, France, Georgia, Germany, Italy, Lithuania, Romania, Slovenia, Spain
<b>No</b>	<b>50% (8 countries)</b> Bulgaria, Czech Republic, Estonia, Germany, Italy,	<b>42% (10 countries)</b> Armenia, Austria, Belgium, Bulgaria, Estonia, Germany,	<b>58% (14 countries)</b> Austria, Bulgaria, Cyprus, Czech Republic,

	Lithuania, Portugal, Serbia	Lithuania, Poland, Portugal, Serbia	Denmark, Estonia, Luxembourg, Norway, Poland, Portugal, Serbia, Slovakia, Switzerland, The Netherlands
<b>I don't know</b>	<b>12% (2 countries)</b> Slovakia, Luxembourg	<b>13% (3 countries)</b> Latvia, Luxembourg, Slovakia	<b>4% (1 country)</b> Malta

**Does the NP/NS for RD of your Country promote the development of innovative methodologies tailored for clinical trials?**

	<b>2020</b>	<b>2021 (no data for Canada and Israel)</b>	<b>2023</b>
<b>Yes</b>	<b>25% (4 countries)</b> Ireland, Lithuania, Portugal, UK	<b>17% (4 countries)</b> Ireland, Italy, Lithuania, UK	<b>12% (3 countries)</b> Canada, Romania, Slovenia
<b>No</b>	<b>56% (9 countries)</b> Bulgaria, Czech Republic, Estonia, Germany, Italy, Luxembourg, Romania, Serbia, The Netherlands	<b>62% (15 countries)</b> Armenia, Austria, Belgium, Bulgaria, Czech Republic, Estonia, Georgia, Germany, Luxembourg, Poland, Portugal, Romania, Serbia, The Netherlands, Turkey	<b>71% (17 countries)</b> Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Georgia, Germany, Italy, Lithuania, Luxembourg, Norway, Portugal, Serbia, Slovakia, Switzerland, The Netherlands
<b>I don't know</b>	<b>19% (3 countries)</b> France, Slovakia, Spain	<b>21% (5 countries)</b> Croatia, France, Latvia, Slovakia, Spain	<b>17% (4 countries)</b> France, Malta, Poland, Spain

**Alignment process of other RD initiatives than the NP/NS for RD with the EJP RD Pillars 1-4<sup>56</sup>**

**Are there other public funding initiatives for research/networking in the field of RD in your country, apart from the NP/NS for RD?<sup>57</sup>**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>81% (13 countries)</b>	<b>65% (17 countries)</b>	<b>28% (7 countries)</b>

<sup>56</sup> Regarding the other RD activities than the NP/NS for RD percentages have been based on 16 countries for 2020, on 26 countries for 2021 and on 25 for 2023

<sup>57</sup> As in the 2020 edition of the survey, and in the elaboration of the updates in 2021 there has been no distinction between national and transnational activities at public/private level, the percentages reported in the tables represent a global presence of other national/transnational activities than those promoted by the NP/NS for RD

	Czech Republic, Estonia, France, Germany, Ireland, Italy, Luxembourg, Portugal, Romania, Slovakia, Spain, The Netherlands, UK	Belgium, Canada, Czech Republic, Estonia, France, Germany, Ireland, Israel, Italy, Luxembourg, Poland, Portugal, Romania, Slovakia, Spain, Turkey, UK	Canada, Cyprus, Romania, Slovenia, Switzerland, The Netherlands, Spain
<b>No</b>	<b>19% (3 countries)</b> Bulgaria, Lithuania, Serbia	<b>23% (6 countries)</b> Austria, Bulgaria, Georgia, Lithuania, Serbia, The Netherlands	<b>40% (10 countries)</b> Bulgaria, Czech Republic, Estonia, Georgia, Germany, Italy, Lithuania, Portugal, Serbia, Slovakia
<b>I don't know</b>	-	<b>12% (3 countries)</b> Armenia, Croatia, Latvia	<b>32% (8 countries)</b> Austria, Denmark, France, Israel, Luxembourg, Malta, Norway, Poland

**Are there private funding initiatives for research/networking in the field of RD in your country?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
	not asked specifically for private national calls	not reported specifically for private national calls	
<b>Yes</b>	<b>56% (9 countries)</b> Bulgaria, France, Germany, Ireland, Italy, Lithuania, Portugal, The Netherlands, UK	<b>46% (12 countries)</b> Belgium, Canada, France, Germany, Ireland, Israel, Italy, Lithuania, Portugal, Spain, The Netherlands, UK	<b>24% (6 countries)</b> Bulgaria, Canada, Germany, Italy, Spain, The Netherlands
<b>No</b>	<b>25% (4 countries)</b> Czech Republic, Estonia, Luxembourg, Serbia	<b>31% (7 countries)</b> Austria, Czech Republic, Estonia, Georgia, Luxembourg, Poland, Serbia	<b>32% (8 countries)</b> Czech Republic, Estonia, Georgia, Lithuania, Serbia, Slovakia, Slovenia, Switzerland
<b>I don't know</b>	<b>19% (3 countries)</b> Romania, Slovakia, Spain	<b>23% (7 countries)</b> Armenia, Bulgaria, Croatia, Latvia, Romania, Slovakia, Turkey	<b>44% (11 countries)</b> Austria, Cyprus, Denmark, France, Israel, Luxembourg, Malta, Norway, Poland, Portugal, Romania

**Pillar 2**

**Are there other public initiatives, than the NP/NS for RD of your country, that support data repositories and tools for research on RD?**

	<b>2020</b>	<b>2021<sup>13</sup></b>	<b>2023</b>
<b>Yes</b>	<b>25% (4 countries)</b> Czech Republic, France, Italy, The Netherlands	<b>42% (11 countries)</b> Belgium, Bulgaria, Canada, Czech Republic, France, Ireland, Italy, Serbia, Spain, The Netherlands, Turkey	<b>24% (6 countries)</b> Bulgaria, Canada, Serbia, Spain, Switzerland, The Netherlands
<b>No</b>	<b>50% (8 countries)</b> Bulgaria, Estonia, Germany, Lithuania, Luxembourg, Portugal, Serbia, UK	<b>39% (10 countries)</b> Austria, Estonia, Georgia, Germany, Israel, Lithuania, Luxembourg, Poland, Portugal, UK	<b>40% (10 countries)</b> Czech Republic, Estonia, Georgia, Germany, Italy, Lithuania, Luxembourg, Portugal, Slovakia, Slovenia
<b>I don't know</b>	<b>25% (4 countries)</b> Ireland, Slovakia, Spain, Romania	<b>19% (5 countries)</b> Armenia, Croatia, Latvia, Romania, Slovakia	<b>36% (9 countries)</b> Austria, Cyprus, Denmark, France, Israel, Malta, Norway, Poland, Romania

**If yes, please specify on which topic (possible multiple choice)<sup>58</sup>**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Registries catalogue</b>	<b>100% (4 countries)</b> Czech Republic, France, Italy, The Netherlands	<b>81% (9 countries)</b> Bulgaria, Canada, Czech Republic, France, Ireland, Italy, Serbia, Spain, The Netherlands	<b>50% (3 countries)</b> Bulgaria, Spain, Switzerland
<b>Biobanks catalogue</b>	<b>50% (2 countries)</b> Italy, The Netherlands	<b>36% (4 countries)</b> Canada, Ireland, Serbia, The Netherlands	<b>33% (2 countries)</b> Spain, The Netherlands
<b>Ontologies and codification</b>	not asked	not asked	-
<b>OMIC services</b>	not asked	not asked	<b>50% (3 countries)</b> Canada, Spain, The Netherlands
<b>Cell lines</b>	<b>25% (1 country)</b> The Netherlands	<b>27% (3 countries)</b> Canada, Serbia, The Netherlands	<b>33% (2 countries)</b> Spain, The Netherlands
<b>Animal models</b>	<b>50% (2 countries)</b>	<b>27% (3 countries)</b>	<b>33% (2 countries)</b>

<sup>58</sup> Percentages referring to the countries answering "Yes" to the previous question

	France, The Netherlands	Canada, France, The Netherlands	Spain, The Netherlands
<b>Semantic standards</b>	<b>25% (1 country)</b> The Netherlands	<b>9% (1 country)</b> The Netherlands	-
<b>Support for clinical/translational research</b>	<b>75% (3 countries)</b> Czech Republic, Italy, The Netherlands	<b>27% (3 countries)</b> Canada, Ireland, The Netherlands	<b>17% (1 country)</b> The Netherlands
<b>Access &amp; privacy control</b>	<b>25% (1 country)</b> The Netherlands	<b>27% (3 countries)</b> Bulgaria, Canada, The Netherlands	<b>33% (3 countries)</b> Canada, The Netherlands
<b>Data deposition and analysis</b>	<b>50% (1 country)</b> France; The Netherlands	<b>45% (5 countries)</b> Bulgaria, Canada, France, Ireland, The Netherlands	<b>33% (3 countries)</b> Canada, The Netherlands
<b>Tools</b>	<b>25% (1 country)</b> The Netherlands	<b>36% (4 countries)</b> Bulgaria, Canada, The Netherlands, Turkey	<b>33% (2 countries)</b> Canada, The Netherlands
<b>Other</b>	-	-	<b>17% (1 country)</b> Serbia

**Are there other private initiatives of your country, that support data repositories and tools for research on RD?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>31% (5 countries)</b> Bulgaria, Italy, Portugal, The Netherlands, UK	<b>23% (6 countries)</b> Bulgaria, Ireland, Italy, Portugal, The Netherlands, UK	<b>20% (5 countries)</b> Bulgaria, Germany, Italy, Spain, The Netherlands
<b>No</b>	<b>38% (6 countries)</b> Czech Republic, Estonia, Ireland, Lithuania, Luxembourg, Serbia	<b>31% (8 countries)</b> Austria, Czech Republic, Estonia, Georgia, Lithuania, Luxembourg, Poland, Serbia	<b>32% (8 countries)</b> Czech Republic, Georgia, Lithuania, Luxembourg, Serbia, Slovakia, Slovenia, Switzerland
<b>I don't know</b>	<b>31% (5 countries)</b> France, Germany, Romania, Slovakia, Spain	<b>46% (12 countries)</b> Armenia, Belgium, Canada, Croatia, France, Germany, Israel, Latvia, Romania, Slovakia, Spain, Turkey	<b>48% (12 countries)</b> Austria, Canada, Cyprus, Denmark, Estonia, France, Israel, Malta, Norway, Poland, Portugal, Romania

**If yes, please specify on which topic (possible multiple choice)<sup>59</sup>**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Registries catalogue</b>	<b>60% (3 countries)</b>	<b>83% (5 countries)</b>	<b>80% (4 countries)</b>

<sup>59</sup> Percentages referring to the countries answering "Yes" to the previous question

	Bulgaria, Portugal, The Netherlands	Bulgaria, Ireland, Italy, Portugal, The Netherlands	Bulgaria, Italy, Spain, The Netherlands
<b>Biobanks catalogue</b>	<b>60% (3 countries)</b> Italy, Portugal, The Netherlands	<b>67% (5 countries)</b> Ireland, Italy, Portugal, The Netherlands	<b>60% (3 countries)</b> Italy, Spain, The Netherlands
<b>Ontologies and codification</b>	not asked	not asked	<b>20% (1 country)</b> Italy
<b>OMIC services</b>	not asked –	not asked	-
<b>Cell lines</b>	<b>40% (2 countries)</b> Portugal, The Netherlands	<b>33% (2 countries)</b> Portugal, The Netherlands	<b>40% (2 countries)</b> Spain, The Netherlands
<b>Animal models</b>	<b>40% (2 countries)</b> Portugal, The Netherlands	<b>33% (2 countries)</b> Portugal, The Netherlands	<b>40% (2 countries)</b> Spain, The Netherlands
<b>Semantic standards</b>	-	-	<b>20% (1 country)</b> Italy
<b>Support for clinical/translational research</b>	<b>40% (2 countries)</b> Bulgaria, The Netherlands	<b>50% (3 countries)</b> Bulgaria, Ireland, The Netherlands	<b>20% (1 country)</b> The Netherlands
<b>Access &amp; privacy control</b>	<b>20% (1 country)</b> The Netherlands	<b>33% (2 countries)</b> Bulgaria, The Netherlands	<b>20% (1 country)</b> The Netherlands
<b>Data deposition and analysis</b>	<b>40% (2 countries)</b> Bulgaria, The Netherlands	<b>67% (4 countries)</b> Bulgaria, Ireland, Italy, The Netherlands	<b>60% (3 countries)</b> Germany, Spain, The Netherlands
<b>Tools</b>	<b>20% (1 country)</b> The Netherlands	<b>50% (3 countries)</b> Bulgaria, Italy, The Netherlands	<b>60% (3 countries)</b> Italy, Spain, The Netherlands
<b>Other</b>	<b>20% (1 country)</b> UK	<b>17% (1 country)</b> UK	-

**Are there other national initiatives for RD, than the NP/NS, that support FAIR\* data? (\*Findable, Accessible, Interoperable, Reusable)**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>50% (8 countries)</b> Czech Republic, France, Germany, Ireland, Italy, Luxembourg, Spain, The Netherlands	<b>35% (9 countries)</b> Belgium, Canada, Czech Republic, France, Germany, Ireland, Italy, Luxembourg, The Netherlands	<b>24% (6 countries)</b> Italy, Portugal, Romania, Slovenia, Switzerland, The Netherlands
<b>No</b>	<b>31% (5 countries)</b>	<b>23% (6 countries)</b>	<b>32% (8 countries)</b>

	Bulgaria, Lithuania, Romania, Serbia, UK	Austria, Georgia, Lithuania, Romania, Serbia, UK	Bulgaria, Czech Republic, Georgia, Lithuania, Luxembourg, Serbia, Slovakia, Spain
<b>I don't know</b>	<b>19% (3 countries)</b> Estonia, Portugal, Slovakia	<b>42% (11 countries)</b> Armenia, Bulgaria, Croatia, Estonia, Israel, Latvia, Poland, Portugal, Slovakia, Spain, Turkey	<b>44% (11 countries)</b> Austria, Canada, Cyprus, Denmark, Estonia, France, Germany, Israel, Malta, Norway, Poland

**Are there other national initiatives, than the NP/NS for RD, that promote the adoption of multidisciplinary approaches for RD?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>63% (10 countries)</b> Bulgaria, France, Germany, Ireland, Italy, Lithuania, Portugal, Romania, Spain, The Netherlands	<b>42% (11 countries)</b> Belgium, Bulgaria, Canada, France, Germany, Ireland, Italy, Latvia, Lithuania, Portugal, Romania	<b>24% (6 countries)</b> Bulgaria, Canada, Italy, Romania, Slovenia, The Netherlands
<b>No</b>	<b>31% (5 countries)</b> Czech Republic, Estonia, Luxembourg, Serbia, UK	<b>31% (8 countries)</b> Austria, Czech Republic, Estonia, Georgia, Luxembourg, Poland, Serbia, UK	<b>32% (8 countries)</b> Czech Republic, Estonia, Georgia, Lithuania, Luxembourg, Portugal, Slovakia, Switzerland
<b>I don't know</b>	<b>6% (1 country)</b> Slovakia	<b>27% (7 countries)</b> Armenia, Croatia, Israel, Spain, Slovakia, The Netherlands, Turkey	<b>44% (11 countries)</b> Austria, Cyprus, Denmark, France, Germany, Israel, Malta, Norway, Poland, Serbia, Spain

**Are there other initiatives, than the NP/NS for RD, that support training activities for RD?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>75% (12 countries)</b> Bulgaria, Czech Republic, Germany, Ireland, Italy, Lithuania, Portugal, Serbia, Slovakia, Spain, The Netherlands, UK	<b>54% (14 countries)</b> Belgium, Bulgaria, Canada, Czech Republic, Germany, Ireland, Italy, Lithuania, Portugal, Serbia, Slovakia, Spain, The Netherlands, UK	<b>24% (6 countries)</b> Bulgaria, Italy, Portugal, Romania, Serbia, The Netherlands
<b>No</b>	<b>6% (1 country)</b> Luxembourg	<b>19% (5 countries)</b> Austria, Georgia,	<b>32% (8 countries)</b> Czech Republic,

		Israel, Luxembourg, Poland	Estonia, Georgia, Lithuania, Luxembourg, Slovakia, Slovenia, Switzerland
<b>I don't know</b>	<b>19% (3 countries)</b> Estonia, France, Romania	<b>27% (7 countries)</b> Armenia, Croatia, Estonia, France, Latvia, Romania, Turkey	<b>44% (11 countries)</b> Austria, Canada, Cyprus, Denmark, France, Germany, Israel, Malta, Norway, Poland, Spain

**Are there other initiatives, than the NP/NS for RD, that promote a rapid translation of research results in clinical studies and healthcare?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>38% (6 countries)</b> Bulgaria, Ireland, Italy, Portugal, The Netherlands, UK	<b>27% (7 countries)</b> Canada, Ireland, Italy, Portugal, The Netherlands, Turkey, UK	<b>12% (3 countries)</b> Italy, Serbia, The Netherlands
<b>No</b>	<b>38% (6 countries)</b> Czech Republic, Estonia, Germany, Lithuania, Luxembourg, Serbia	<b>38% (10 countries)</b> Austria, Czech Republic, Estonia, Georgia, Germany, Israel, Lithuania, Luxembourg, Poland, Serbia	<b>32% (8 countries)</b> Czech Republic, Bulgaria, Georgia, Lithuania, Luxembourg, Portugal, Slovakia, Slovenia
<b>I don't know</b>	<b>24% (4 countries)</b> France, Romania, Slovakia, Spain	<b>35% (9 countries)</b> Armenia, Belgium, Bulgaria, Croatia, France, Latvia, Romania, Slovakia, Spain	<b>56% (14 countries)</b> Austria, Canada, Cyprus, Denmark, Estonia, France, Germany, Israel, Malta, Norway, Poland, Romania, Spain, Switzerland

**EU-13 Countries<sup>60</sup>**

**Is there an approved NP/NS for RD in your country?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes (active, expired,</b>	<b>86% (6 countries)</b>	<b>80% (8 countries)</b>	<b>90% (9 Countries)</b>

<sup>60</sup> In 2020 Hungary replied to the survey, but there are no other information than the ongoing development of the NP/NS for RD at the time of the data collection. The country has therefore been considered only for the percentages of the question on the existence of a NP/NS for RD. Hence, it has been considered that in 2020, 6 EU-13 Countries participated to the survey, in 2021, 9 EU-13 Countries and in 2023, 10 EU-13 Countries. The percentage incidences of this section on EU-13 Countries have been calculated by the above cited number of participants per year



<b>under renewal)</b>	Bulgaria, Czech Republic, Estonia, Lithuania, Romania, Slovakia	Bulgaria, Croatia, Czech Republic, Estonia, Latvia, Lithuania, Romania, Slovakia	Bulgaria, Cyprus, Czech Republic, Estonia, Lithuania, Poland, Romania, Slovakia, Slovenia
<b>No</b>	-	-	-
<b>It is under approval/development</b>	<b>14% (1 country)</b> Hungary	<b>20% (2 countries)</b> Hungary, Poland	<b>10% (1 countries)</b> Malta
<b>I don't know</b>	-	-	-

**Pillar 1**

**Does the NP/NS for RD of your country promote national calls for research projects?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	-	<b>34% (3 countries)</b> Croatia, Latvia, Romania,	<b>60% (6 countries)</b> Cyprus, Czech Republic, Lithuania, Romania, Slovakia, Slovenia
<b>No</b>	<b>67% (4 countries)</b> Bulgaria, Estonia, Lithuania, Romania	<b>56% (5 countries)</b> Bulgaria, Czech Republic, Estonia, Lithuania, Poland	<b>30% (3 countries)</b> Bulgaria, Estonia, Poland
<b>I don't know</b>	<b>33% (2 countries)</b> Czech Republic, Slovakia	<b>11% (1 country)</b> Slovakia	<b>10% (1 country)</b> Malta

**Does the NP/NS for RD of your country promote transnational calls for research projects?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>17% (1 country)</b> Czech Republic	<b>34% (3 countries)</b> Croatia, Czech Republic, Romania	<b>60% (6 countries)</b> Cyprus, Czech Republic, Lithuania, Portugal, Romania, Slovakia
<b>No</b>	<b>66% (4 countries)</b> Bulgaria, Estonia, Lithuania, Romania	<b>44% (4 countries)</b> Bulgaria, Estonia, Lithuania, Poland	<b>40% (4 countries)</b> Bulgaria, Estonia, Poland, Slovenia
<b>I don't know</b>	<b>17% (1 country)</b> Slovakia	<b>22% (2 countries)</b> Latvia, Slovakia	<b>10% (1 country)</b> Malta

**Does the NP/NS for RD of your country foresee investments to share knowledge?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>33% (2 countries)</b> Bulgaria, Lithuania	<b>34% (3 countries)</b> Bulgaria, Croatia,	<b>40% (4 countries)</b> Cyprus, Lithuania,

		Lithuania	Poland, Slovenia
<b>No</b>	<b>50% (3 countries)</b> Czech Republic, Estonia, Romania	<b>22% (2 countries)</b> Estonia, Poland	<b>50% (5 countries)</b> Bulgaria, Czech Republic, Estonia, Romania, Slovakia
<b>I don't know</b>	<b>17% (1 country)</b> Slovakia	<b>44% (4 countries)</b> Czech Republic, Latvia, Romania, Slovakia	<b>10% (1 countries)</b> Malta

**Pillar 2**

**Does the NP/NS for RD of your country support data repositories and tools for re-search on RD?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>50% (3 countries)</b> Czech Republic, Lithuania, Romania	<b>56% (5 countries)</b> Bulgaria, Croatia, Czech Republic, Lithuania, Romania,	<b>80% (8 countries)</b> Bulgaria, Estonia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia
<b>No</b>	<b>33% (2 countries)</b> Bulgaria, Estonia	<b>22% (2 countries)</b> Estonia, Poland	<b>10% (1 country)</b> Cyprus
<b>I don't know</b>	<b>17% (1 country)</b> Slovakia	<b>22% (2 countries)</b> Latvia, Slovakia	<b>10% (1 country)</b> Czech Republic

**If the NP/NS for RD of your country supports data repositories and tools for research on RD, please specify the topic (possible multiple choice)<sup>61</sup>**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Registries catalogue</b>	<b>100% (3 countries)</b> Czech Republic, Lithuania, Romania	<b>100% (5 countries)</b> Bulgaria, Croatia, Czech Republic, Lithuania, Romania,	<b>88% (7 countries)</b> Bulgaria, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia
<b>Biobanks catalogue</b>	<b>33% (1 country)</b> Czech Republic	<b>40% (2 countries)</b> Czech Republic, Lithuania	<b>38% (3 countries)</b> Lithuania, Malta, Slovenia
<b>Ontologies and codification</b>	<b>67% (2 countries)</b> Czech Republic, Lithuania	<b>60% (3 countries)</b> Croatia, Czech Republic, Lithuania	<b>38% (3 countries)</b> Lithuania, Poland, Slovenia
<b>OMIC services</b>	-	-	<b>13% (1 country)</b> Lithuania
<b>Cell lines</b>	-	-	-
<b>Animal models</b>	-	-	-

<sup>61</sup> Percentages referring to the countries answering "Yes" to the previous question.

Semantic standards	-	-	<b>13% (1 country)</b> Poland
Support for clinical/translational research	<b>33% (1 country)</b> Czech Republic	<b>20% (1 country)</b> Czech Republic	<b>50% (4 countries)</b> Lithuania, Malta, Romania, Slovenia
Access & privacy control	<b>33% (1 country)</b> Lithuania	<b>40% (2 countries)</b> Bulgaria, Lithuania	<b>13% (1 country)</b> Lithuania
Data deposition and analysis	<b>33% (1 country)</b> Lithuania	<b>40% (2 countries)</b> Bulgaria, Lithuania	<b>25% (2 countries)</b> Lithuania, Poland
Tools	<b>33% (1 country)</b> Lithuania	<b>40% (2 countries)</b> Bulgaria, Lithuania	<b>13% (1 country)</b> Lithuania
Other	-	-	-

**Does the NP/NS for RD of your country support FAIR\* data? (Findable, Accessible, Interoperable, Reusable)**

	2020	2021	2023
Yes	-		<b>50% (5 countries)</b> Lithuania, Poland, Romania, Slovakia, Slovenia
No	<b>67% (4 countries)</b> Bulgaria, Czech Republic, Lithuania, Romania	<b>56% (5 countries)</b> Bulgaria, Czech Republic, Lithuania, Poland, Romania	<b>30% (3 countries)</b> Bulgaria, Cyprus, Estonia
I don't know	<b>33% (2 countries)</b> Estonia, Slovakia	<b>44% (4 countries)</b> Croatia, Estonia, Latvia, Slovakia	<b>30% (3 countries)</b> Czech Republic, Malta

**Does the NP/NS for RD promote the adoption of multidisciplinary/holistic approaches for RD?**

	2020	2021	2023
Yes	<b>50% (3 countries)</b> Bulgaria, Lithuania, Romania	<b>67% (6 countries)</b> Bulgaria, Croatia, Latvia, Lithuania, Poland, Romania	<b>80% (8 countries)</b> Bulgaria, Cyprus, Estonia, Lithuania, Poland, Romania, Slovakia, Slovenia
No	<b>33% (2 countries)</b> Czech Republic, Estonia	<b>22% (2 countries)</b> Czech Republic, Estonia	<b>10% (1 country)</b> Czech Republic
I don't know	<b>17% (1 country)</b> Slovakia	<b>11% (1 country)</b> Slovakia	<b>10% (1 country)</b> Malta

**Does the NP/NS for RD of your country promote training activities for RD?**

	2020	2021	2023
Yes	<b>66% (4 countries)</b> Bulgaria, Czech	<b>67% (6 countries)</b> Bulgaria, Croatia	<b>100% (countries)</b> Bulgaria, Cyprus,

	Republic, Lithuania, Romania	Czech Republic, Lithuania, Poland, Romania	Czech Republic, Estonia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia
<b>No</b>	<b>17% (1 country)</b> Estonia	<b>22% (2 countries)</b> Estonia, Latvia	-
<b>I don't know</b>	<b>17% (1 country)</b> Slovakia	<b>11% (1 country)</b> Slovakia	-

**If yes, on which topics? (Possible multiple choice)<sup>62</sup>**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Data management</b>	<b>50% (2 countries)</b> Bulgaria, Lithuania	<b>50% (3 countries)</b> Bulgaria, Czech Republic, Lithuania	<b>30% (3 countries)</b> Lithuania, Malta, Poland
<b>Data quality</b>	<b>50% (2 countries)</b> Bulgaria, Lithuania	<b>33% (2 countries)</b> Bulgaria, Lithuania	<b>30% (3 countries)</b> Czech Republic, Malta, Poland
<b>FAIR data</b>	-	-	<b>10% (1 country)</b> Poland
<b>Standards and quality of genetics/genomics data in clinical practice and laboratories</b>	<b>100% (4 countries)</b> Bulgaria, Czech Republic, Lithuania, Romania	<b>83% (5 countries)</b> Bulgaria, Czech Republic, Lithuania, Poland, Romania	<b>30% (3 countries)</b> Czech Republic, Lithuania, Poland
<b>Registries</b>	<b>75% (3 countries)</b> Bulgaria, Czech Republic, Lithuania	<b>100% (6 countries)</b> Bulgaria, Croatia, Czech Republic, Lithuania, Poland, Romania	<b>60% (6 countries)</b> Bulgaria, Malta, Poland, Romania, Slovakia, Slovenia
<b>Biobanks</b>	<b>25% (1 country)</b> Lithuania	<b>33% (2 countries)</b> Lithuania, Poland	<b>10% (1 country)</b> Poland
<b>Empowerment of the patients</b>	<b>100% (4 countries)</b> Bulgaria, Czech Republic, Lithuania, Romania	<b>100% (6 countries)</b> Bulgaria, Croatia, Czech Republic, Lithuania, Poland, Romania	<b>80% (8 countries)</b> Bulgaria, Cyprus, Czech Republic, Estonia, Poland, Romania, Slovakia, Slovenia
<b>Online education courses</b>	<b>75% (3 countries)</b> Czech Republic, Lithuania, Romania	<b>67% (4 countries)</b> Czech Republic, Lithuania, Poland, Romania	<b>50% (5 countries)</b> Bulgaria, Cyprus, Czech Republic, Poland, Romania

<sup>62</sup> Percentages referring to the countries answering "Yes" to the previous question.

<b>Other</b>	<b>25% (1 country)</b> Lithuania	<b>17% (1 country)</b> Lithuania	<b>10% (1 country)</b> Estonia
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**Pillar 4**

**Does the NP/NS for RD of your country promote a rapid translation of research results in clinical studies and healthcare?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>17% (1 country)</b> Romania	<b>34% (3 countries)</b> Croatia, Czech Republic, Romania	<b>30% (3 countries)</b> Lithuania, Romania, Slovenia
<b>No</b>	<b>66% (4 countries)</b> Bulgaria, Czech Republic, Estonia, Lithuania	<b>44% (4 countries)</b> Bulgaria, Estonia, Lithuania, Poland	<b>60% (6 countries)</b> Bulgaria, Cyprus, Czech Republic, Estonia, Poland Slovakia
<b>I don't know</b>	<b>17% (1 country)</b> Slovakia	<b>22% (2 countries)</b> Latvia, Slovakia	<b>10% (1 country)</b> Malta

**Does the NP/NS for RD of your Country promote the development of innovative methodologies tailored for clinical trials?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>17% (1 country)</b> Lithuania	<b>11% (1 country)</b> Lithuania	<b>20% (2 countries)</b> Romania, Slovenia
<b>No</b>	<b>66% (4 countries)</b> Bulgaria, Czech Republic, Estonia, Romania	<b>56% (5 countries)</b> Bulgaria, Czech Republic, Estonia, Poland, Romania	<b>60% (6 countries)</b> Cyprus, Czech Republic, Estonia, Georgia, Lithuania, Slovakia
<b>I don't know</b>	<b>17% (1 country)</b> Slovakia	<b>33% (3 countries)</b> Croatia, Latvia, Slovakia	<b>20% (2 countries)</b> Malta, Poland

**Alignment process of other RD initiatives than the NP/NS for RD with the EJP RD Pillars 1-4<sup>63</sup>.**

**Are there other public funding initiatives for research/networking in the field of RD in your country, apart from the NP/NS for RD?<sup>64</sup>**

	<b>2020</b>	<b>2021</b>	<b>2023</b>

<sup>63</sup> The percentages of this section have been calculated on 6 EU-13 Countries for 2020, on 9 EU-13 Countries for 2021 and on 10 EU-13 Countries for 2023.

<sup>64</sup> As in the 2020 edition of the survey, and in the elaboration of the updates in 2021 there has been no distinction between national and international activities at public/private level, the percentages reported in the tables represent a global presence of other activities than those promoted by the NP/NS for RD on the specific item

<b>Yes</b>	<b>67% (4 countries)</b> Czech Republic, Estonia, Romania, Slovakia	<b>56% (5 countries)</b> Czech Republic, Estonia, Poland, Romania, Slovakia	<b>30% (3 countries)</b> Cyprus, Romania, Slovenia
<b>No</b>	<b>33% (2 countries)</b> Bulgaria, Lithuania	<b>22% (2 countries)</b> Bulgaria, Lithuania	<b>50% (5 countries)</b> Bulgaria, Czech Republic, Estonia, Lithuania, Slovakia
<b>I don't know</b>	-	<b>22% (2 countries)</b> Croatia, Latvia	<b>50% (5 countries)</b> Malta, Poland

**Are there private funding initiatives for research/networking in the field of RD in your country?**

	<b>2020<sup>65</sup></b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>33% (2 countries)</b> Bulgaria, Lithuania	<b>11% (1 country)</b> Lithuania	<b>10% (1 country)</b> Bulgaria
<b>No</b>	<b>33% (2 countries)</b> Czech Republic, Estonia	<b>33% (3 countries)</b> Czech Republic, Estonia, Poland	<b>50% (5 countries)</b> Czech Republic, Estonia, Lithuania, Slovakia, Slovenia
<b>I don't know</b>	<b>33% (2 countries)</b> Romania, Slovakia	<b>56% (5 countries)</b> Bulgaria, Croatia, Latvia, Romania, Slovakia	<b>40% (4 countries)</b> Cyprus, Malta, Poland, Romania

**Are there other public initiatives, than the NP/NS for RD of your country, that support data repositories and tools for research on RD?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>17% (1 country)</b> Czech Republic	<b>22% (2 countries)</b> Bulgaria, Czech Republic	<b>10% (1 country)</b> Bulgaria
<b>No</b>	<b>50% (3 countries)</b> Bulgaria, Estonia, Lithuania	<b>34% (3 countries)</b> Estonia, Lithuania, Poland	<b>50% (5 countries)</b> Czech Republic, Estonia, Lithuania, Slovakia, Slovenia
<b>I don't know</b>	<b>33% (2 countries)</b> Slovakia, Romania	<b>44% (4 countries)</b> Croatia, Latvia, Romania, Slovakia	<b>40% (4 countries)</b> Cyprus, Malta, Poland, Romania

**If yes, please specify on which topic (possible multiple choice)<sup>66</sup>**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Registries catalogue</b>	<b>100% (1 country)</b> Czech Republic	<b>100% (2 countries)</b> Bulgaria, Czech	<b>100% (1 country)</b> Bulgaria

<sup>65</sup> Rounding does not allow to reach 100%

<sup>66</sup> Percentages referring to the countries answering "Yes" to the previous question.

		Republic	
<b>Biobanks catalogue</b>	-	-	-
<b>Ontologies and codification</b>	not asked	not asked	-
<b>OMIC services</b>	not asked	not asked	-
<b>Cell lines</b>	-	-	-
<b>Animal models</b>	-	-	-
<b>Semantic standards</b>	-	-	-
<b>Support for clinical/translational research</b>	<b>100% (1 country)</b> Czech Republic	-	-
<b>Access &amp; privacy control</b>	-	<b>100% (2 countries)</b>	-
<b>Data deposition and analysis</b>	-	<b>100% (2 countries)</b>	-
<b>Tools</b>	-	<b>50% (2 countries)</b> Bulgaria	-
<b>Other</b>	-	-	-

**Are there other private initiatives of your country, that support data repositories and tools for research on RD?**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Yes</b>	<b>17% (1 country)</b> Bulgaria	<b>22% (1 country)</b> Bulgaria	<b>10% (1 country)</b> Bulgaria
<b>No</b>	<b>50% (3 countries)</b> Czech Republic, Estonia, Lithuania	<b>44% (4 countries)</b> Czech Republic, Estonia, Lithuania, Poland	<b>4% (4 countries)</b> Czech Republic, Lithuania, Slovakia, Slovenia
<b>I don't know</b>	<b>33% (2 countries)</b> Romania, Slovakia	<b>44% (4 countries)</b> Croatia, Latvia, Romania, Slovakia	<b>5% (5 countries)</b> Cyprus, Estonia, Malta, Poland, Romania

**If yes, please specify on which topic (possible multiple choice)<sup>67</sup>**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Registries catalogue</b>	<b>(1 country)</b> Bulgaria	<b>(1 country)</b> Bulgaria	<b>(1 country)</b> Bulgaria
<b>Biobanks catalogue</b>	-	-	-

<sup>67</sup> Percentages referring to the countries answering "Yes" to the previous question.

Ontologies and codification	not asked	not asked	-
OMIC services	not asked –	not asked	-
Cell lines	-	-	-
Animal models	-	-	-
Semantic standards	-	-	-
Support for clinical/translational research	<b>(1 country)</b> Bulgaria	<b>(1 country)</b> Bulgaria	-
Access & privacy control	-	<b>(1 country)</b> Bulgaria	-
Data deposition and analysis	<b>(1 country)</b> Bulgaria	<b>(1 country)</b> Bulgaria	-
Tools	-	<b>(1 country)</b> Bulgaria	-
Other	-	-	-

**Are there other national initiatives for RD, than the NP/NS, that support FAIR\* data? (\*Findable, Accessible, Interoperable, Reusable)**

	2020	2021	2023
<b>Yes</b>	<b>17% (1 country)</b> Czech Republic	<b>11% (1 country)</b> Czech Republic	<b>20% (2 countries)</b> Romania, Slovenia
<b>No</b>	<b>50% (3 countries)</b> Bulgaria, Lithuania, Romania	<b>22% (2 countries)</b> Lithuania, Romania	<b>40% (4 countries)</b> Bulgaria, Czech Republic, Lithuania, Slovakia
<b>I don't know</b>	<b>33% (2 countries)</b> Estonia, Slovakia	<b>67% (6 countries)</b> Bulgaria, Croatia, Estonia, Latvia, Poland, Slovakia	<b>40% (4 countries)</b> Cyprus, Estonia, Malta, Poland

**Are there other national initiatives, than the NP/NS for RD, that promote the adoption of multidisciplinary approaches for RD?**

	2020	2021	2023
<b>Yes</b>	<b>50% (3 countries)</b> Bulgaria, Lithuania, Romania	<b>44% (4 countries)</b> Bulgaria, Latvia, Lithuania, Romania	<b>30% (3 countries)</b> Bulgaria, Romania, Slovenia
<b>No</b>	<b>33% (2 countries)</b> Czech Republic, Estonia	<b>34% (3 countries)</b> Czech Republic, Estonia, Poland	<b>40% (4 countries)</b> Czech Republic, Estonia, Lithuania, Slovakia
<b>I don't know</b>	<b>17% (1 country)</b> Slovakia	<b>22% (2 countries)</b> Croatia, Slovakia	<b>30% (3 countries)</b> Cyprus, Malta, Po-



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**Are there other initiatives, than the NP/NS for RD, that support training activities for RD?**

	2020	2021	2023
<b>Yes</b>	<b>67% (4 countries)</b> Bulgaria, Czech Republic, Lithuania, Slovakia	<b>44% (4 countries)</b> Bulgaria, Czech Republic, Lithuania, Slovakia	<b>20% (2 countries)</b> Bulgaria, Romania
<b>No</b>	-	<b>12% (1 country)</b> Poland	<b>50% (2 countries)</b> Czech Republic, Estonia, Lithuania, Slovakia, Slovenia
<b>I don't know</b>	<b>33% (2 countries)</b> Estonia, Romania	<b>44% (4 countries)</b> Croatia, Estonia, Latvia, Romania	<b>30% (3 countries)</b> Cyprus, Malta, Poland

**Are there other initiatives, than the NP/NS for RD, that promote a rapid translation of research results in clinical studies and healthcare?**

	2020	2021	2023
<b>Yes</b>	<b>17% (1 country)</b> Bulgaria	-	-
<b>No</b>	<b>50% (3 countries)</b> Czech Republic, Estonia, Lithuania	<b>44% (4 countries)</b> Czech Republic, Estonia, Lithuania, Poland	<b>50% (5 countries)</b> Bulgaria, Czech Republic, Lithuania, Slovakia, Slovenia
<b>I don't know</b>	<b>33% (2 countries)</b> Romania, Slovakia	<b>56% (5 countries)</b> Bulgaria, Croatia, Latvia, Romania, Slovakia	<b>50% (5 countries)</b> Cyprus, Estonia, Malta, Poland, Romania

**Based on your experience, what are the main obstacles and barriers in your country for the development, improvement and translation of RD research results? (Possible multiple choice)**

	2020	2021	2023
<b>Language</b>	<b>17% (1 country)</b> Slovakia	<b>11% (1 country)</b> Slovakia	-
<b>Funding</b>	<b>83% (5 countries)</b> Bulgaria, Czech Republic, Estonia, Lithuania, Romania	<b>89% (8 countries)</b> Bulgaria, Croatia, Czech Republic, Estonia, Latvia, Lithuania, Poland, Romania	<b>90% (9 countries)</b> Bulgaria, Cyprus, Czech Republic, Estonia, Lithuania, Malta, Poland, Romania, Slovakia
<b>Difficulties in accessing to national resources for fund-</b>	<b>50% (3 countries)</b> Czech Republic, Lithuania, Romania	<b>56% (5 countries)</b> Bulgaria, Croatia, Latvia, Lithuania,	<b>80% (8 countries)</b> Bulgaria, Cyprus, Lithuania, Malta,

ing research and development of RD projects		Romania	Romania, Poland, Slovakia, Slovenia
Lack of options	<b>50% (3 countries)</b> Czech Republic, Estonia, Lithuania	<b>22% (2 countries)</b> Estonia, Lithuania	<b>20% (2 countries)</b> Malta, Romania

**Regarding your participation in EU/International projects in the RD field, what do you estimate to be the most important/obstacles and barriers? (Possible multiple choice)**

	<b>2020</b>	<b>2021</b>	<b>2023</b>
<b>Lack of information on funding opportunities</b>	<b>57% (4 countries)</b> Czech Republic, Estonia, Lithuania, Romania	<b>56% (5 countries)</b> Estonia, Latvia, Lithuania, Poland, Romania	<b>40% (4 countries)</b> Cyprus, Malta, Romania, Slovakia
<b>Limited links to potential partners</b>	<b>86% (6 countries)</b> Bulgaria, Czech Republic, Estonia, Lithuania, Romania, Slovakia	<b>78% (7 countries)</b> Bulgaria, Croatia, Czech Republic, Estonia, Lithuania, Romania, Slovakia	<b>40% (4 countries)</b> Bulgaria, Cyprus, Lithuania, Malta
<b>Bureaucratic application on responding procedures</b>	<b>43% (3 countries)</b> Czech Republic, Estonia, Romania	<b>56% (5 countries)</b> Bulgaria, Croatia, Czech Republic, Estonia, Romania	<b>80% (8 countries)</b> Bulgaria, Cyprus, Czech Republic, Estonia, Malta, Romania, Poland, Slovakia
<b>Irrelevance of programme topics and goals to own research agenda</b>	<b>14% (1 country)</b> Lithuania	<b>22% (2 countries)</b> Lithuania, Poland	<b>10% (1 country)</b> Lithuania
<b>Quality of support provided by national contact points</b>	<b>43% (3 countries)</b> Czech Republic, Romania, Slovakia	<b>22% (2 countries)</b> Czech Republic, Slovakia	<b>50% (5 countries)</b> Czech Republic, Malta, Romania, Poland, Slovenia