EJP RD
European Joint Programme on Rare Diseases

H2020-SC1-2018-Single-Stage-RTD
SC1-BHC-04-2018
Rare Disease European Joint Programme Cofund

Grant agreement number 825575

Del 10.3
Third Annual strategic report and Action plan for Pillar 2, including:
Systematic surveys reports, QMS of Pillar 2 description, GDPR compliance report and sustainability planning reporting

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Due date of deliverable: month 33

Dissemination level:
Public
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1. Pillar 2 Third Annual Strategic Report

1.1. Reminder of Pillar 2 background and concept

Pillar 2 was designed to mainly contribute with one of the major objectives of the EJP RD: To improve the integration, the efficacy, the production, and the social impact of research on RD through the development, demonstration, and promotion of Europe-wide and even world-wide sharing of research and clinical data, materials, processes, knowledge, and know-how. More precisely, Pillar 2 has been set to create an innovative coordinated access to data and services for transformative RD research aiming at rationalizing, optimizing, and increasing potential of existing resources and services, and to address the gaps on data essential to enable multidisciplinary, holistic approaches for rare disease diagnostics and therapeutics by fostering creation of complete disease pathways.

Pillar 2 is creating a sustainable and interoperable ecosystem of resources (the EJP RD virtual platform, or VP in short), coupled to robust standards, tools and procedures that will infuse FAIR principles into advanced and secure forms of data discovery, linkage and sharing. It will allow flexible, real-time access to data (under suitably controlled conditions), with supporting tools and services that serve the ultimate goal of increasing the efficiency and efficacy of RD research. Driven by concrete use-cases and needs arising from the RD clinical and research community, not least ERNs, it will provide the means to harmonise and standardise the way RD relevant data, samples, tools, and other relevant resources are made findable, accessible, interoperable, and re-usable, and the means to query the progressively increasing number of resources and repositories connected to the EJP RD virtual platform through a central facility.

Pillar 2 strategy is to establish a stronger and broader collaboration between the RD community and European Research Infrastructures and global consortia. This will have major mutual benefit and impact. On the one hand, RD research, supported by patient representatives and ERNs, presents an exemplar challenge and opportunity for research infrastructures to create common solutions and stimulate collaboration. On the other hand, progress in RD research depends on the strongest possible infrastructure to address its needs towards efficient information retrieval and analysis across its distributed data resources. The increased capacity of infrastructures and their seamless integration with the RD community will ultimately translate to higher innovation potential and benefit for patients.

The final product of Pillar 2, namely the VP, will therefore allow to centrally query a myriad of heterogeneous resources, as well as build a federated discoverability, query, and analysis network by promoting the progressive FAIRification of data sources, including multi-omics rare disease pathways created by Pillar 2 itself.

1.2. Methods

1.2.1. Reminder of Pillar 2 thematic structure

Pillar 2 work was organized in 4 Work Packages (WPs) around 4 main themes:

1. Overall coordination

WP10: User-driven strategic planning and transversal activities for Pillar 2 data ecosystem, which provides the critical ‘coordination and navigation’ role for the Virtual Platform, where users (especially ERNs) will participate as key leaders and decision makers, and ensures that the work in Pillar 2 (WP11, WP12 and WP13) is synergised and optimised.
2. Making resources usable for RD research

WP11: **Common virtual platform for discoverable data and resources for RD research**, of which the main aim is to tackle fragmentation of data repositories, catalogues, resources and tools, by: (i) building a comprehensive, FAIR-compliant virtual platform extensively describing resources with their metadata (including registries, biobanks, research infrastructures, genome-phenome repositories, methods, standards, etc.) allowing for these resources to be findable online via a central access point and (ii) providing researchers the means to deposit, share and analyse phenotypic, genomic and multi-omics data in a harmonised, standardised manner, building-on and scaling-up existing resources, which will be findable through the virtual platform (VP) as well.

3. Making record-level data usable for RD research

WP12: **Enabling sustainable FAIRness and federation at the record level for RD data, patients, and samples**, which will develop and apply procedures, standards, and tools, with the RD community to achieve FAIRness at the record level. This will enable clinical and biological researchers to discover useful and usable data with high specificity across resources, assess access restrictions for specific data quickly (e.g., consent, data usage licenses), and develop powerful analysis across multiple resources without delay caused by data incompatibilities.

4. Making system biology approach data usable for RD research

WP13: **Enabling multidisciplinary, holistic approaches for rare disease diagnostics and therapeutics**, which objectives are directed at filling the gaps that currently make it hard to perform multi-omics analysis on rare diseases. The aim of multi-omics analysis is ultimately to find better diagnostics (for instance process biological based panels) and to develop better therapies.

1.2.2. Reminder of Pillar 2 operational organization

According to the First Pillar 2 strategic plan (Del. 10.1), tasks and subtasks have been aligned to cross-task teams called Work Foci Teams (WFT). Indeed, since the different components of the VP should be consistently developed towards making resources, records and data findable and queryable in a coordinated manner, organizing the work-by-work Foci (WF) allows related tasks to be conducted together in a more efficient and coherent way. WFs do not replace tasks and subtasks as per the Description of Work (DoW) in the Grant Agreement (GA) but make them work together towards a common objective therefore optimizing the use of resources. Tasks and subtasks not fitting a specific WF are conducted as expected as per the GA’s DoW.

WF teams (WFTs) work according to the Agile methodology involving both Pillar 2 partners and ERNs designated representatives for each of them. This will allow for cycles of development and testing. Further delineation of WFs will be done as the project evolves in a flexible way. Experiences from field-testing based on use cases ensure that Pillar 2 developments fit the needs of users and have the expected impact on accelerating research. The Overall Architecture (OA) WF ensures the global consistency of the VP components according to the VP specifications that are thus elaborated collaboratively. Below the short description of WFs’ objectives:

- **Use cases WF**: setting up research questions by committed stakeholders, including ERN partners that will drive the development of VP components based on real-world needs;
1.3. Strategic plan

1.3.1. Continue increasing visibility and awareness concerning EJP RD available resources to foster RD research

Further to the launch of a mind map-like webpage allowing users to easily discover the resources that are either EJP RD partners, either IRDiRC Recognized Resources, or...
both (https://resourcemap.ejprarediseases.org/#/), the series of webinars about each one of these resources will continue and documentation will be produced.

1.3.2. Integrating the Work Foci’s Virtual Platform building blocks
As the project evolves, the components of the VP developed by the different WF teams should be integrated together in order to deliver the first operational releases of the VP. To this end, cross-WF work will be conducted, represented by the black lines in the Figure below, in order to:

- Bridge the resource-level and the record-level metadata models and expand the query possibilities using those models, thus expanding the variables to be included in the queries. It will allow for discovery of resources (i.e., catalogues of registries, and registries) and of records within the resources (i.e., counts of patients with some characteristics). This goal will be achieved by Metadata WF and Query Builder WF cross-work, specifically conducting on purpose query builder pilots.

- Allow for discovery of resources for data deposition and analysis, as well as of FAIR disease pathways created in WP13, through the VP: it will need common work between Resources for sharing experimental data and materials WF, Pathway creation and curation WF, Metadata WF and Query Builder WF.

- Allow for data analysis using the conceptual models built in WP13 within data analysis platforms. To this end, Resources for experimental data and analysis interpretation WF, Pathway creation and curation WF, Genetic variants pathways WF, Environment/Adverse outcome pathways WF and Biological networks analysis methods WF will collaborate together.

- Build the VP access control common facilities, joining the work of Distributed and federated consent control WF, Authentication Authorisation Infrastructure WF and Personal data linkage service WF.

![Figure 1. Cross-WP organization in WFs, with cross-WF integration represented as black lines](image-url)
1.3.3. Expanding functional and non-functional requirements for VP components development: Virtual Platform Specifications (VIPS)

In order to obtain a functioning and robust EJP RD Virtual Platform, the VIPS specifies a framework, including implementation and interoperability conditions, to be considered by developers of software components that need to function with multiple resources in the VP infrastructure. Interoperability is here considered in its wider meaning, encompassing its technical, semantic, and legal and organisational aspects, including identification, evaluation, selection, and endorsement of a growing set of standards.

VIPS includes non-functional requirements. Non-functional requirements encompass criteria VP technical components should be compliant to in order to achieve an increasingly consistent, internally interoperable, Virtual Platform. These requirements include Quality, Sustainability, Scalability, Data Protection (GDPR), Consent Management, FAIRification. Dedicated WFs or working groups, some transversal with non-Pillar 2 working groups (Sustainability, Consent control, GDPR) will work at releasing guidelines.

Enhanced releases of the VIPS will be developed.

1.3.4. Conducting consistent development workflow for integrated VP components towards production release of the VP first version

Further to the development of individual VP components, a methodology for their integration and release of the first version of the VP will be developed. It will include retro-engineering with pilot products as a starting point, in order to reformulate or identify use cases (by the Use case WF) allowing for the definition of the minimum functionalities to be included in the first version of the VP. These use cases will be the basis for testing the Minimum Valuable Products (MVPs). Overall architecture (OA) WF team will ensure compliance with the VIPS and supervise the whole process.

Further development plans will be set up in order to define the subsequent VP versions according to the same methodology. Internal milestones will be defined and recorded in the Pillar 2 Masterplan.

1.3.5. Enlarging the VP to other prioritised resources in a federated manner

In order to get EJP RD partner resources represented in the VP metadata model, and to allow these resources to be discoverable and queryable through the VP, a new set of resources are prioritized each year. As a reminder, catalogues of registries, biobanks and tools were prioritized in year 1 (Orphanet, BBMRI, RD-Connect Biobank and Registry Finder, JRC’s ERDRI and ELIXIR bio.tools), resources providing support for translational and clinical research were prioritized in year 2 (the Innovation Management Toolbox developed within WP19, EATRIS and ECRIN), and resources collecting or producing animal models and cell lines (INFRAFRONTIER, Cellosaurus, hPSCreg) were prioritized in year 3.

Working with these resources allow for expanding the VP resource-level metadata model, as well as to create FAIR Data Point sat the resource level, making them amenable to be queried through the VP central gate, but also from any other end of the VP discoverability network in a federated manner.

Following the 3rd Annual Retreat, Pillar 2 partner knowledge bases (Rare disease WikiPathways, UniProt/NeXtProt, Metabolights, RDMKit and Orphadata) are prioritized.
The ontological metadata model and the resources-level query builder will be expanded in order to make them findable and queryable through the VP.

1.3.6. Expanding the EJP RD FAIRification stewardship programme
The FAIRification stewardship program initiated to accompany ERNs’ registries development in a standardized, VP-compliant way, will be extended to other resources such as genomes (e.g., for the Beyond one-million genome initiative – B1MG), cell lines, stem cells, and analysis (workflows, results, provenance).

This program is operating within the FAIRification WF and includes building a FAIR Stewards Team, developing a FAIRification roadmap, and a set of supporting documentation, an inventory of standards and tools and FAIRification procedures, including a Smart guidance for FAIR data stewards, as well as learning modules and materials.

1.3.7. Tackling the secure accessibility and reusability challenge
The VP network needs to ensure secure access and reusability for resources and data in it. Single sign-on authentication and access authorisation technology, based on Life Science AAI should be deployed across VP partner resources, in particular patient registries, biobanks and genomics and multi-omics deposition and analysis resources. Furthermore, machine-readability of access conditions and consent clauses should be standardised based on existing ontologies adapted to the specific needs of the VP. Furthermore, privacy-preserving record linkage technologies should be implemented, but the compatibility and interoperability of the diverse existing solutions pose a particular challenge.

As an essential component of the VP, access and consent control services will be further developed by the integrated work of the three WFs involved.

1.3.8. Expanding Pillar 2 external collaborations to promote an interoperable RD research network of resources in Europe and beyond
Partnerships with ongoing initiatives that are complementary to Pillar 2 developments, in order to increase VP interoperability capabilities and ultimately contribute at creating the conditions for RD research both at the European level and internationally. Partnership will intend to develop common use cases. In particular, collaborations with the Critical Path Institute (C-Path), Beyond 1 Million Genomes project (B1MG), X-eHealth, ERICA, EOSC-Life, and the European Health Data Space will be initiated or reinforced. They will aim at harmonising the use of semantic and technical standards, at developing data model transformation methods, and/or at developing further a federated framework across projects.

1.3.9. Improving and developing further data deposition and analysis facilities
Improvements in the adaptation of non-RD specific resources (i.e., INFRAFRONTIER, Cellosaurus, hPSCreg, and others) to RD have been made and will continue to allow interconnexion between complementary resources and, i.e., allowing to query a resource from another one, with the goal to streamline researcher’s search experience. Data deposition and analysis resources will be made also queryable from the VP, in the frame of the integration of WFs developments.

The development of a cloud-based solution for custom analysis will continue by expanding the EJP RD Virtual Cluster, in close collaboration between WP11 and WP13.
In particular, Variant interpretation, whole exome, and multi-omics analysis methods will be established as separate pipelines (using a standard pipeline language and containerization) to automate future analyses. These developments will be made publicly available and registered to be findable in the UMCG Virtual Cluster Environment (VRE). New analysis capabilities and tools will be developed in EJP RD analysis platforms in response to users’ needs collected during webinars.

1.3.10. Enhancing and expanding RD pathways creation and analysis based on case studies, and making them findable through the Virtual Platform

X-omics workflows, tools and training materials that have been developed will continue to be included on the virtual platform, and interconnected to data deposition and analysis resources (see section above), to progressively build a streamlined research pathways linking phenomics, genomics and X-omics data to enhance findability and usability of data resources in EJP RD. It will allow creating a catalogue of multi-omics integration tools that should help RD researchers to decide which tools to apply in which situation. This integrative work will be performed by leveraging ELIXIR Bundle-services and bio.tools capacities, and will be instrumental in making these different resources working together within the Virtual Platform.

Rare diseases pathway creation and curation according to use cases will continue. In particular, multi-omics as well as network and pathway-based analysis approaches will be used to identify biomarkers and disease modifiers such as nutrition and environmental factors.

Based on pilot work on current three case studies, profile of necessary tools, workflows, data, and analysis results will be created. A new round of case studies will be selected from Pillar 1 funded projects towards the identification of shared disease mechanisms and druggable pathways across rare diseases (initiating a collaboration with the new IRDiRC taskforce on shared molecular aetiologies), selection of drug repurposing candidates, and identification of (environmental and genetic) disease modifiers explaining differences in disease severity and penetrance.
2. Users survey report

In year 3 no major Community survey was launched, as the task focused on capturing use cases from stakeholders. In this regard, and leveraging the close collaboration with Pillar 1 and research projects funded by the Joint Transnational Calls (JTC), analyses were performed to review research needs in these funded projects.

Pillar 2 participated in the mid-term review of JTC 2018 mid-term monitoring meeting and in the kick-off of JTC 2020 projects to have a closer overview of the ongoing research and potential needs. In these occasions, Pillar 2 Virtual Platform concept, existing tools and resources were presented to the researchers.

2.1. Joint Transnational Call 2020 Research Projects

Pillar 2 participated in the kick-off meeting of the research projects funded under the JTC 2020 call. The 2020 call topic was “Pre-clinical Research to Develop Effective Therapies for Rare Diseases” in which 18 projects were selected for funding. The abstracts of these projects were analysed for the type of biological materials or models used for research, whether -Omic approaches were used, and data types which may be supported by Pillar 2 resources. Given the call focused on pre-clinical studies, all the projects mentioned use of animal models or use of patient cells as model for research. Out of 18 projects, 7 indicated -omics studies (3 transcriptomics, 1 proteomic, 1 metabolomic, 1 epigenome and 1 multi-omics). Three projects are interested in understanding molecular signatures or pathways of diseases, and 2 more projects examining nutrition and -omics interplay in diseases. These projects indicate particular relevance of tools being developed in WP13.

Table 1. Disease models and data types used or collected by JTC 2020 funded projects.

<table>
<thead>
<tr>
<th>Models</th>
<th>Mice, rabbit, cell lines, neuronal stem cells, patient cells, organoids, iPSCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data types</td>
<td>Phenotypes, biomarkers, mutations, genes, behaviour, nutrition, omics (transcriptomics, proteomics, metabolomic, epigenome)</td>
</tr>
</tbody>
</table>

2.2. Joint Transnational Call 2018 Research Projects

The topic of the JTC 2018 call was “hypothesis-driven use of multi-omics integrated approaches for discovery of disease causes and/or functional validation in the context of rare diseases”. The mid-term review meeting on the progress of the 12 funded projects took place online on 20 May 2021. Pillar 2 was present at the meeting to present the available resources, in particular the tools related to multiomic and system biology analyses. Information on the type of -omics platform used in the research projects were extracted from project lay summaries. All or nearly all of the projects indicated use of transcriptomic and proteomic platforms.

Table 2: Different -omics platforms being used in the JTC 2018 projects.
Table 2. Different -omics platforms being used in the JTC 2018 projects

<table>
<thead>
<tr>
<th>Platform / Infrastructure</th>
<th>No. of projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcriptomics</td>
<td>12</td>
</tr>
<tr>
<td>Proteomics</td>
<td>11</td>
</tr>
<tr>
<td>Genomics</td>
<td>9</td>
</tr>
<tr>
<td>Epigenomics</td>
<td>7</td>
</tr>
<tr>
<td>Metabolomics</td>
<td>4</td>
</tr>
<tr>
<td>Pathogenic read-outs of disease groups</td>
<td>4</td>
</tr>
</tbody>
</table>

A targeted questionnaire was sent to the JTC 2018 researchers during and after the mid-term review meeting to capture more information on the projects and interest to collaborate with Pillar 2. The poll contained questions related to samples, technologies used for multi-omics data generation and analysis. Out of 12 funded projects, 4 submitted a response to the additional questionnaire. The interest to collaborate with WP13 for use cases are to be followed up by relevant Work Foci and partners.
3. GDPR implementation in Pillar 2 report

3.1. Background
Compliance with GDPR and data protection regulations in a broader sense is one of the clear goals of the EJP RD Virtual Platform (VP). The overall regulatory oversight in the project is provided by the AREB. The purpose of Task T10.3 is to prepare practical guidance for the Pillar 2 for regulatory compliance and ensure consistency across the Pillar 2 how compliance is achieved.

In the first two years of the EJP RD, the task T10.3 on technical monitoring and coordination of GDPR implementation has focused on providing methodological guidance for those implementing services that are or need to become compliant to GDPR.

3.2. Methods
In the third year of the EJP RD project, where the Virtual Platform finalized the first stage of development and is being launched, the T10.3 has shifted toward monitoring the GDPR compliance. For this purpose, information on services that are becoming part of the Virtual Platform needs to be collected and particularly aspects related to data protection, such as information on legal persons operating services, roles of the legal persons with respect to the data (controller/processor) types of data being processed, legal bases used for processing for data controllers, and information on application of privacy enhancing technologies.

A data model describing these aspects has been designed, reviewed by the consortium and a first version has been implemented using Molgenis platform and first real-world data has been filled in for testing purposes. The service is available at [http://ejp-rd-catalog.tools.bbmri-eric.eu/](http://ejp-rd-catalog.tools.bbmri-eric.eu/). The implementation is now being tested and updated based on the pilot phase feedback and will be populated at scale with the services constituting the EJP RD Virtual Platform.
3.3. Achievements

- Design and review of the data model.
- Implementation of the first version of the GDPR compliance monitoring service using Molgenis platform.

3.4. Next steps

- Populate and curate the information on services constituting EJP RD.
4. Quality oversight report

4.1. Problem
To assess the quality (fitness for purpose) of the tools and resources in Pillar 2 applying the quality criteria identified in year 1.

4.2. Background
The quality criteria were refined following an initial trial and incorporated into a draft Quality Policy. Following approval this will be added to the VIPS document.

4.3. Methods and Achievements
The criteria were used to design a Form to simplify the collection of data from each resource. The first round gathered publicly available data on those resources listed in the Non-Functional RD Bundle which confirmed the approach was effective. A second round gathered data from more than 90 resources with all data made available in a working table. The data gathered supplements information from the regular presentations by different resources as part of the regular Non-Functional calls.

4.4. Next Steps
- The Form was refined after two rounds of data gathering, further changes could be considered.
- To tidy up the working table, filling in gaps
- Identify further resources associated with the VP and gather information
- Engage with WP3 Element Cards to disseminate information
- Identify overlaps with Standards Tools
5. Sustainability oversight report

5.1. Problem

Many of the outputs of the EJP RD, including Pillar 2’s, will have value when the project ends. Each of these outputs will require explicit thoughts on how they will be sustained after the project. Sustainability in a public health program is important for four main reasons: (1) sustained programs can maintain their effects for a long time, (2) there is often a latency period between the beginning of program-related activities and their effects on population health, (3) absence of sustainability can lead to an investment loss for the organisations and people involved, and (4) discontinuation of program-related activities may bring disillusion to participants and make subsequent community mobilisation difficult. In order to give a long-term perspective to actions contributing to visibility, registration, surveillance, and knowledge dissemination of RD, there is a need to use legal and funding tools.

5.2. Background

Without a proper sustainability plan, any services or other resources that are created in a project may no longer be systematically developed and maintained after the project. In that case, they will be losing their value, and potentially have to be redeveloped in new projects. To prevent such a thing from happening to the EJP RD VP and its services, financing models to sustain and scale up the development and use of the VP are being studied. Program implementation and sustainability should not be distinct and successive phases but should be concomitant processes in order to consider the recursive or reflexive character of sustainability and learning or of the continuous adjustments that shape the sustainability process.

5.3. Methods

We plan to organise reviews between the participants in the architecture Work Focus and experts on sustainability, in order to make sure that sustainability aspects are considered whenever architectural decisions are made.

5.4. Achievements so far

The work on sustainability in WP10 is done in close collaboration with the transversal WP3 dedicated to sustainability. The original list of elements that require sustainability that has been shared from Pillar 2 with WP3 has been extended, and information is being detailed further. This will serve to help the WP3 approach to sustainability, which is based on survey and interviews and on benchmarking versus the EJP RD sustainability handbook.

The WP10 approach that was chosen earlier, complementary to WP3, has been to let each of the providers of components of the Virtual Platform fill in a presentation template in which aspects for software components that are important for sustainability and quality are highlighted, and discuss these completed presentations in a meeting with Pillar 2 experts on the Virtual Platform and on Quality and sustainability. Goal of these presentations is to identify potential weaknesses in quality and sustainability that can be addressed or that need to be mitigated in order for the entire virtual platform not to depend critically on a brittle connection. The template that is to be used for these presentations has now been completed, and thus far two components have been discussed in the group. Furthermore, the considerations that
are part of the template are explained in the formal description of the Virtual Platform (VIPS).

5.5. Next steps
In the coming time, we will plan and execute the presentations for more of the components of the Virtual Platform.