EIRENE PPP

Horizon Europe

Project: 101079789

D4.1 – EIRENE RI Access procedures to be tested

Document Information

Grant Agreement Number	101079789	Acronym	EIRENE PPP
Full title	EIRENE PPP		
Project URL	https://www.eirene.eu/		
Project Officer	Andreas Holtel, Andreas.HOLTEL@ec.europa.eu		

Delivery date	Contractual	30/09/2024	Actual	30/09/2024
Status		Version_0.4 (Sept 27th 2024)		
Nature		DEC		
Dissemination level		Public		

Responsible Partner	UNIVIE		
Responsible Author	Benedikt Warth	E-mail	benedikt.warth@univie.ac.at
	Partner	UNIVIE	Phone	+43-(0)664-817-6222
Other authors	Jan J. Stiglitz, Vinicius V. Hernandes, Max L. Feuerstein		

Document History

Institution	Date	Version
UNIVIE	15/08/2024	v.01
UNIVIE	30/08/2024	v.02
UNIVIE	11/09/2024	v.03
UNIVIE	26/09/2024	v.04
UNIVIE	27/09/2024	V1.0 FINAL

Table of Contents

Abstract

Europe is currently grappling with unprecedented challenges in public health, the environment, the economy, society, and politics. Issues such as an aging population, environmental pollution, energy crises, climate change, and the recent COVID-19 pandemic call for innovative, robust, and sustainable solutions. These solutions require interdisciplinary collaborations, robust technical and human resources, meaningful (harmonized and validated) data, and relevant expertise. Despite the massive amounts of environmental and health data collected due to advancements in equipment and storage, inconsistencies arise from poor sampling and collection techniques. Additionally, regional disparities in European capacities, a lack of standardization, and limited access procedures also hinder effective data utilization.

These challenges catalyzed the creation of the **EIRENE RI, the Research Infrastructure for EnvIRonmental Exposure assessmeNt in Europe**. This long-term project, highlighted in the 2021 Update of the **European Strategic Forum on Research Infrastructure (ESFRI) Roadmap**, aims to develop technical and intellectual capacities for comprehensive research on the health effects of environmental stressors throughout life. The preparatory project phase (PPP) seeks to establish a consolidated European research infrastructure to develop advanced technologies and services for characterizing complex environmental exposures and their impacts on the European population. The objective is to enhance European excellence in Environmental & Health research by providing researchers with transnational and/or virtual access to harmonized capacities, unique services, and comprehensive data that meet the current and future needs of public authorities. The **EIRENE PPP project** unites leading international experts and institutions to prepare **EIRENE RI** for full implementation.

The **preparatory phase** aims to ensure EIRENE RI achieves the legal, financial, organizational, and technical readiness required for implementation. This phase will focus on identifying national hubs and their members, defining the key pillars of the EIRENE RI architecture, establishing topical nodes and related services, conducting an inventory of national capacities, introducing the management structure, and defining core facilities, services, and user access strategies. Given the significant impact EIRENE RI is expected to have on health protection and chemical safety, and its relevance for policy-making and international treaty implementation, its stakeholder community includes major international organizations and agencies. All stakeholder categories will be represented in the Stakeholders' Forum and, if relevant, the Users' Forum.

Stakeholders are crucial to EIRENE RI, especially during the preparatory phase, as the research infrastructure embodies the concept of **Open Science**, integrating previously scattered capacities into an efficient network. Open Science practices are central to EIRENE RI's implementation. The infrastructure will offer physical and remote transnational access (TNA) to its facilities (e.g., laboratories) and access to data and services via **virtual access (VA)**. A user access framework will be designed to provide effective, transparent, tailored, and user-friendly access, delivering high-quality services to a broad community of users, including scientists, policymakers, private companies, health providers, NGOs, and citizens.

Customized tools will be developed to meet the diverse needs of the broad potential user community. The preparatory phase will ensure that EIRENE RI achieves the necessary legal, financial, organizational, and technical maturity for implementing these tools. These efforts are encapsulated in WP4, as outlined in the strategic document of the EIRENE RI-PPP[1].

---

[1] Call: [HORIZON-INFRA-2021-DEV-02-01] — [Developing & consolidating the European research infrastructures landscape, maintaining global leadership (2021), Grant: Preparatory phase of new ESFRI research infrastructure projects].

1. Introduction

1.1.   WP4 Overview and Objectives

As outlined in the grant proposal, the activities for WP4 were initiated in Year 2 of the Preparatory Phase Project. The reason for this timing was the need to build upon the initial outcomes of WP1 (*vision and strategy*) and, in particular, WP2 (*development of services*). Based on these outcomes, a pilot for future users' access to the EIRENE RI services shall be designed.

To prepare for the EIRENE pilot, the participation of national core facilities that are ready to be deployed, as identified in T2.2, is essential. These facilities will help initiate the setup of access tools and test access procedures for physical, remote, and virtual access as outlined in T2.3. The pilot's findings will provide valuable feedback to WP2, aiding in the further refinement of the user access framework as the research infrastructure develops.

However, the full execution of the pilot—meaning actual user access to EIRENE RI capacities and services— is beyond the scope of the preparatory phase. Instead, the functionality of access to select EIRENE core capacities will be simulated, with selected national node partners participating based on their high levels of administrative and technical readiness.

1.2.   WP4 Deliverables

D4.1 EIRENE RI Access procedures to be tested [M24]
D4.2 EIRENE RI facilities to be used in the Pilot – report [M24]
D4.3 EIRENE RI pilot design and tools [M35]

1.3.   Task T4.1: Definition and preconditions

Task 4.1 (*EIRENE RI Access Procedures to be Tested*; UW, all partners, M13-36) focuses on developing a framework and procedures to **enable various categories of users to access EIRENE services.**

The foundation for this task is based on the outcomes of WP2, specifically Task T2.3[2], which aims to create a system facilitating access for both direct and indirect users to the services provided by the EIRENE RI pillars. In essence, **Task 4.1 will establish the rules and procedures** governing user access to the core services identified in Task T2.1 of WP2.

---

[2] Ibidem.
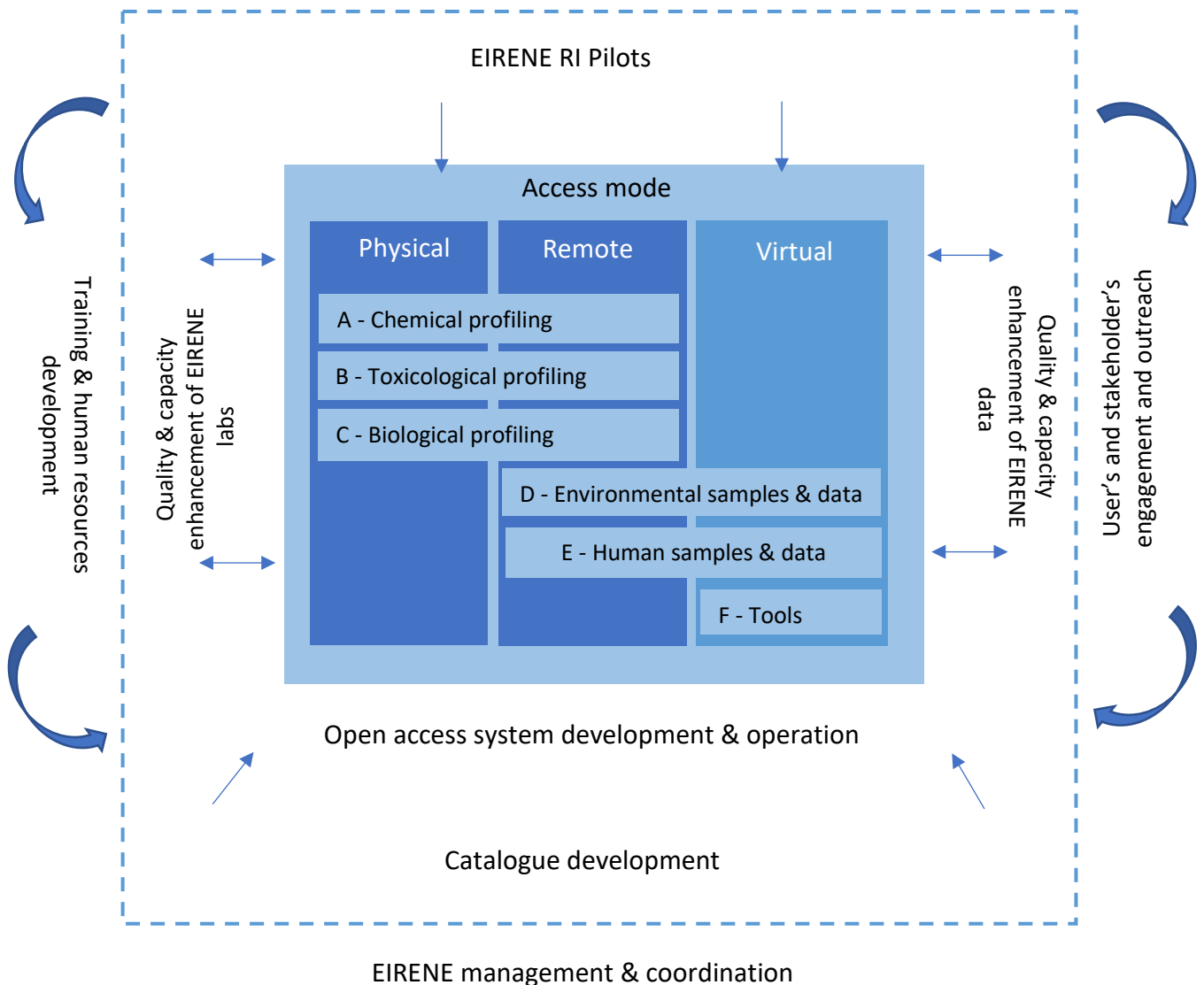
Sustainable model of EIRENE services

Figure 1. The EIRENE pillar structure includes six distinct pillars (A-F) divided into two categories, the physical or remote Trans-National Access (1) and the Virtual Access (2) to the EIRENE services.

In defining access to EIRENE services, as outlined in Table 2, WP2 had to address the high complexity and diverse nature of the services[3] offered across the pillars, requiring specific tailored approaches. A key **priority was to draw on processes established by existing ESFRI** infrastructures and national facilities, while also consulting a broad range of stakeholders (T8.2), including direct and indirect users, as well as funding authorities.

As stated in the project proposal, the design of the pilot exercise will be reviewed in consultation with the potential user community identified in T8.2[4].

---

[3] i.e. access to laboratory capacities and services, networks and cohorts, their samples and data, models, and IT tool.

[4] T8.2: *Stakeholder engagement* (VITO, all partners, M1-36)

Table 2. Pillar structure of the 10 EIRENE core services and their corresponding domains.[5]

Pillars		Access mode			Domain	EIRENE services classification
		Physical	Remote	Virtual		
A	Chemical profiling	✓	✓		Laboratory capacities for chemical profiling (selective / non-selective data acquisition)	(Target/non-target) measurement of exogenous substances (parent compound and transformation products) and their mixtures in the environment and human biofluids and tissues
B	Toxicological profiling	✓	✓		Laboratory capacities for hazard assessment (non-animal toxicological models to test toxicity of chemicals, their mixtures & environmental samples	Quantification/determination of toxicity (human and eco-adverse outcome pathways and modes of action in-vivo, ex-vivo, in-vitro, in-silico)
C	Biological Profiling	✓	✓		Laboratory capacities for biological profiling (elucidating the impact of toxic exposures on health)	Omics-based markers of biological response (both MS-based and sequencing technologies), e.g., (epi)genomics, transcriptomics, metagenomics/microbiomics, proteomics, metabolomics, lipidomics, adductomics
D	Environmental data & samples		✓	✓	Data from large-scale longitudinal environmental (air, indoor, soil, food, consumer products – on-site, remote, satellite) monitoring for assessing the external exposome	Databases and portals presenting environmental (pollutants, temperature, noise), exposure maps, and other tools that can be further combined with socioeconomic and/or lifestyle data Biobanked samples enabling delivery of such data Access to monitoring networks enabling collection of such data/samples
E	Human data & samples		✓	✓	Data from longitudinal population cohorts covering various groups, cross-sectional studies, health surveys, and clinical studies as an information source on population exposure and health	Databases and portals presenting human environmental (chemical biomonitoring, temperature, noise) and socioeconomic exposure, behaviour, lifestyle, and health data Biobanked samples enabling delivery of such data Access to population studies enabling collection of such data/samples
F	Tools			✓	Data management, processing, federated analysis, modeling, and presentation tools and platforms, computational capacities and virtual laboratories	Fair cataloguing of exposome data (e.g., cohorts, algorithms) Biostatistical and/or bioinformatics tools and platforms for investigating exposome-human health interactions

---

[5] Page 4 of the document *Deliverable D2.1 – List of EIRENE core services, WP – Development of services, WP Leader UU, submitted March 2024.*

1.4. A domain set for WP4 by the outcomes of T2.2

In the EIRENE pilot, we will engage **national core facilities identified in T2.2 that are ready to be deployed through EIRENE at this moment**.

This task aimed to **prepare an inventory of existing services, identifying synergies and gaps**. Partners from Utrecht University utilized the list of EIRENE RI core services developed in T2.1, assessing the services already provided by national node research infrastructures and evaluating their extent and readiness to be offered via Open Access.[6]

This work provided **key input for the gap analysis and a draft plan for the development of EIRENE RI services**, which was the main outcome of this task. The implementation roadmap devised in T1.4, including proposed quality management schemes and harmonization criteria, was also considered. Following, this will inform WP7 (Financial Planning) for the development of the EIRENE RI financial plan, and WP4 for the design of the EIRENE RI pilot.

Open Access refers to the availability of services offered across the six EIRENE pillars. From this, we need to identify the <u>access procedures</u> and <u>access facilities</u> that will be tested in the pilot. The deliverable of WP4 explains the focus on specific providers and services for the pilot phase.

Lastly, it is important to note that this deliverable will outline only the key steps that need to be addressed and identify areas requiring further development. The concrete decision-making and execution of specific actions fall outside the scope of this deliverable.

Context:

The EIRENE PPP coordinator, RECETOX, has a fully functional OA procedure in place for their national RI that should be adapted for the needs of the pan-European EIRENE RI.

2. Elements of the access procedures

The elements to be tested in the pilot include the following key topics:

1. **Open Access**[7] *(software)*: A tool will be developed to guide users and manage requests simultaneously, functioning as both a front-end interface and a back-office system to handle request management. The online application process will be managed through the Central Hub at MU, following the model of the established national node access point (https://openaccess.recetox.cz/) and extending it to the pan-European RI.

2. **Development of a (reduced) catalogue and presentation of the portfolio** to enable free browsing of EIRENE services:

    i. The catalogue will be the only section of the *EIRENE Open Access web interface* accessible without a login, allowing users to freely explore the services without any restriction. This ensures that interested users can easily browse the offerings without prior intent or commitment.

---

[6] This inventory was developed in collaboration with T1.2 and T1.3 mapping the national capacities (and capacities in existing ESFRI projects and landmarks) in all EIRENE RI pillars.

[7] Not a subject of this deliverable. By the end of PPP period, it is expected to be completed and later launched in the implementation phase.

ii. The remaining sections of the web interface will, however, require login access. This enables the OA manager to track user interactions, such as inquiries (via the service desk) and collaboration interests. Registration will be necessary for tracking purposes and **for building the EIRENE user community**.

iii. **Reduced catalogue:** it will solely be worked on an updated catalogue of services based on the level of readiness during the fall 2024, however for the purposes of this deliverable it will be reduced.

3. **Login, Help Desk** and **Service Pre-selection mechanism[8]**

i. **User Support and Help Desk**: This feature should be tested by the end of the PPP, allowing potential future users to directly ask questions, consult with the EIRENE OA manager, and submit queries via email. Establishing a fully functional help desk early on is crucial to provide timely user support.

ii. **Capacity Allocation**: Potential users should be able to express a preference for a national node to provide the service, though the final decision will be upon the RI Open Access manager and the evaluation committee.

For the pilot phase, allocation of capacities will be simplified[9], with only one service provider per service assigned, as the main objective is to test procedures only. As a result, this step is excluded from the pilot phase, and a formal process for assigning users to service providers when multiple options are available **will be developed in the future**.

4. **Development of rules and guidance** of how **users propose a specific project**:

Users will request **not only** *services* but also the *resources* and *capacities* of the RI. Therefore, a preliminary review is needed to ensure the proposal is feasible based on the RI's available capacities.

Once verified, the proposal can be submitted to the scientific board for a thorough evaluation, considering factors such as *scientific innovation, merit, number of samples, measurement methods,* or *data types*.

A balanced approach is essential, requiring enough information for the board's assessment while keeping the proposal process user-friendly. A concise proposal form should be developed as part of the access procedures to be tested.

5. **Development of the Evaluation Criteria, Committees, and Procedures**: *What bodies shall evaluate proposals*?

i. **Evaluation Criteria:** Proposal evaluation will consist of two steps: *Feasibility* and *Scientific Quality*:

(1) Feasibility: The scientific board should only invest time in proposals that are <u>feasible</u> and for which the research infrastructure has adequate capacity. Therefore, an initial assessment by the OA manager, in collaboration with the heads of the relevant distributed infrastructures, is necessary to confirm the proposal's feasibility.

---

[8] A detailed procedure of how to resolve this task will be decided in the future. Deliverable 4.1 only identifies all the key elements that need to be considered in the pilot.

[9] As for now, we have only limited knowledge about who can provide the services because our service list rather contains *capabilities*, and not the *services* per se. There is still a lack of information about everyone´s capacities, accreditation, certification, and resources to provide the service and the list is somehow theoretical. This gap (who has the capacity to provide the service if we have the users) should be filled in about two years from now.

(2) Scientific Quality: Once feasibility is confirmed, the proposal will be forwarded to the evaluation committee, which will consist of scientists.

   ii. **Evaluation Period (Frequency)**: The evaluation committee is expected to meet periodically (e.g., quarterly), while proposals can be submitted and pre-checked by the OA manager on an ongoing basis (continuously).

   iii. **Committee Composition**: The selection committee will include the heads of EIRENE facilities or other assigned scientific representatives, ensuring a broad perspective across various scientific disciplines and national nodes.

   iv. **Procedure**: Proposals will be submitted to the OA manager via the web interface. After consulting with the facility manager to confirm feasibility, the proposal will be forwarded to the evaluation board.

6. **Priority Setting: Criteria for Evaluating Proposals**

   i. **Preference for First-time Applicants**: In alignment with the ESFRI goal to engage and serve a diverse user base, EIRENE will prioritize first-time users.

   ii. **Scientific Challenge**: EIRENE's capacity will primarily be allocated to outstanding research projects characterized by high innovation and relevance. While routine requests may be considered if they come from reputable institutions and offer substantial financial contributions, a significant portion of the RI capacity will be reserved for ambitious projects.

   iii. **Private vs. Public Sector**: EIRENE will allow private businesses to access up to 20% of its capacity, provided their proposed projects demonstrate *innovative qualities*.

7. **Differences Between Transnational, Remote, and Virtual Access:** The procedures will vary based on the type of Open Access (OA):

i. **Transnational (Physical):** In this mode, the user visits the RI in person. For example, a PhD student may conduct measurements on project samples under the supervision of an EIRENE expert in an EIRENE laboratory facility.

ii. **Remote**: This involves the circulation of materials, where users send their samples to an RI laboratory for analysis.

iii. **Virtual**: This type of access focuses on data analysis and the use of data tools, allowing users to engage with the RI's resources without needing to be physically present.

8. **Ratio Between Routine and Novel Services & Development:**
   - Approximately 20-30% of the RI capacity will be dedicated to technology development and the establishment of new services.
   - The costs associated with these developments should primarily be funded by national sources, while Open Access (OA) services will be financed through EU service grants. Active communication with RI clients will help identify future needs, which will inform the creation of new developments and services.

9. **Preliminary Approval (Project Proposals) vs. Immediate Service:**

   i. **Option 1 – Consult *Before* Submission**: Users often consult with the RI prior to submitting a project proposal to a third-party funding agency to avoid developing a project that is not feasible. This is particularly important because, with a typical *funding success rate of only 20%*, the RI could become overwhelmed with applications that ultimately do not receive funding. Nonetheless, it remains essential for users to engage with the RI before submission to ensure feasibility.

   ii. **Option 2 – Consult *After* Submission:** In this scenario, users inform the RI of their intention to utilize its capacity after submitting a project for third-party funding. They later return to request services from the RI based on their project proposal, without the RI having seen the proposal beforehand. This lack of prior consultation can create complications.

   iii. **Conclusion:** Some procedure is still necessary for pre-checking preliminary proposals, while users must proactively communicate the timelines and decisions of their funders to ensure proper capacity allocation.

10. **Financial Conditions (Flat or Varied):** The RI needs to know upfront whether the user can cover the associated user fees from their own resources, is applying for funding, or is requesting that the RI cover their project costs. The RI may have specific projects that support analyses for certain users.

    i. **INFRA-SERV Projects:** These projects cover EIRENE-RI service requests. If an applicant presents a financially secure situation for their project (e.g., a clinical project with collected samples and available resources for analysis), it would be a straightforward case for the RI. However, this raises questions about the evaluation criteria: *should the RI prioritize such financially stable projects even if they may not be as high in quality or challenge level?*

    ii. **Routine Proposals**: If a user submits a routine proposal that is financially secured, the RI may adopt a more *lenient* approach, provided there is available capacity at that time. Accepting such applications would be legitimate in this context.

    iii. **Relation to Scientific Excellence and Public vs. Private Sector**[10]**:** This discussion ties into the broader evaluation of scientific excellence and the distinctions between public and private sector contributions.

11. **MTA and DTA Forms, Data Ownership, and Open Science Principles:** Each user request involving the transfer of material must be supported by a signed *Material Transfer Agreement* (MTA) and followed by the return of data with a *Data Transfer Agreement* (DTA).

    i. **Development of a Standardized Template for the Entire RI**: A standardized template for MTAs and DTAs needs to be created, requiring consultation with the legal departments of each RI member to establish a universally acceptable solution for all the RI members.

    ii. **Timeframe**: Like all other documents drafted during the PPP phase, these agreements will be subject to updates and upgrades. The legal consultation process can begin during the PPP by requesting each facility to provide their

---

[10] If the RI has limited capacity, with a high demand for the services, the preference is **always** given to scientific excellence, especially in the cases when the RI finances are invested.

existing MTA templates, which a central legal team will review and suggest modifications for. All finalized requirements will be submitted to the Italian team from CNR (WP3), which will incorporate them into the relevant documents.

iii. **Permanent solution**: A permanent solution would involve the RI administration assigning services, leaving it to each service-providing facility to manage the associated MTAs. As long as the agreements align with the legal procedures of the respective facility, the RI does not need to concern itself with the specifics of the MTA used, making this the simplest approach since each facility already has its own MTA.

iv. **Considering the Open Science Dimension**: While MTAs and DTAs are essential for protecting data owners, the entire RI should actively promote the principle of *open science*. Most funding from the INFRA Calls comes from the EOSC, which mandates that all data be openly accessible.

Therefore, a procedure for sharing raw data must be developed. Although this will not be incorporated into the Pilot due to time constraints before the end of the PPP, **a consensus should be sought during this phase to guide future efforts**.

- If the RI covers the access fees for a user, the EIRENE facility should be designated as the owner of the data produced. The service-providing facility must ensure that the data is accessible and reportable to the central office. All data generated with EIRENE funding should adhere to the FAIR principles (*Findable, Accessible, Interoperable,* and *Reusable*) as outlined by the EOSC.

- A potential *delay period* of up to three years may be implemented to allow the user to publish their findings before the data is made public. However, after this period, all data should be publicly accessible. This approach ensures that public resources are not used to create a competitive advantage for any institution that requested the service.

- Even if a service is funded by a user, it will be mandatory for the raw data to be publicly available. The RI will actively promote this principle as a positive example of *open science*. Furthermore, the level of data openness may be incorporated into the evaluation criteria for proposals.

12. **User Training (On-Site and Online):** User training is particularly important for those accessing services physically, but online training will also be provided to ensure comprehensive support for all users.

13. **Publication Outcomes, Authorship, and Acknowledgment:** Upon a positive evaluation of a proposal, the contract outlining the provided services will specify the required acknowledgments and potential authorship for any resulting publications or theses. This contract will also include a requirement for open access to raw data.

14. **Evaluation of Services and Monitoring:** Each user will be required to complete a standardized evaluation form following their service experience. Documentation of (open) access, including formal contracts, streamlined feedback, and report forms, will be integrated into the EIRENE Key Performance Indicators (KPIs), which will be established at a later stage.

3. Key elements to be tested in PPP

It is proposed to test only the selected elements (1-6, and 9th) of the described 14 elements when piloting the procedures at the end of the preparatory phase project.

4. Acknowledgments

The team of the University of Vienna would like to thank all partners who supported the work in WP4. A special thanks to the national node lead of Czechia and the Netherlands and their teams.

5. ANNEXES

Annex 1 Description of CZ national node access point and procedures.

Annex 2: Draft of the EIRENE Open Access System (EOAS)

```
                    ┌──────────────────┐
                    │ Service selection│
                    └──────────────────┘
                             │
                             ▼
                    ┌──────────────────┐
                    │  Registration /  │
                    │     sign-in      │
                    └──────────────────┘
                             │
                             ▼
                    ┌──────────────────┐
                    │     Proposal     │
                    │    submission    │
                    └──────────────────┘
                             │
                             ▼
                      ◇ Scientific & Technical
                        evaluation
                        (feasibility/capacity) ◇
                             │
                             ▼
                      ◇ Funding source ◇
                             │
                             ▼
                      ◇ Facility
                        appointment ◇
                             │
                             ▼
                    ┌──────────────────┐
                    │ Project/Service  │
                    │ contract         │
                    │ negotiation &    │
                    │ signature ("GAP")│
                    └──────────────────┘
                             │
                             ▼
                    ┌──────────────────┐
                    │     Project      │
                    │  implementation  │
                    └──────────────────┘
                             │
                             ▼
                     ( Project results )

  ● User driven
  ● EIRENE driven
```