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Table of Contents

Abstract	4
1. Introduction	5
1.1. WP4 Objectives	5
1.2. WP4 Deliverables	5
1.3. Task T4.2: Definition and preconditions	5
1.4. A domain set for WP4 by the outcomes of T2.2	8
2. Identifying the facilities and services to be offered through the EIRENE RI Pilot	8
2. Selection of facilities and services to be tested in the pilot	10
3. Acknowledgments	11
4. ANNEXES	11
Annex 1	11
Annex 2	12

Abstract

Europe faces unprecedented public health, environmental, economic, social, and political challenges, such as ageing population, environmental pollution, energy crisis, climate change or the Covid-19 pandemic of the past years. Tackling such complex and global issues requires innovative, robust, and sustainable solutions, which can be achieved only through interdisciplinary collaborations, the availability of technical and human capacities, meaningful (harmonized and validated) data, and relevant know-how. However, while environmental and health data are collected in massive amounts attributable to rapid improvements in equipment and storage capacities, these data are often inconsistent due to poor sampling and collection designs and techniques. Besides, significant regional gaps in European capacities, lack of standardization, and limited users' access procedures hinder their meaningful use.

These circumstances were among the major triggers for initiating the **EIRENE RI, the Research Infrastructure for Environmental Exposure assessment in Europe**. This long-term project, prioritized in the 2021 Update of the European Strategic Forum on Research Infrastructure (ESFRI) Roadmap, aims at the **development of technical and intellectual capacities facilitating comprehensive research on the life-course health effects of environmental stressors**. Its preparatory project phase (PPP) strives to prepare a consolidated European research infrastructure enabling the development of advanced technologies and complementary services on the characterization of complex environmental exposures and their impact on the European population. The goal is to promote European excellence in Environmental & Health research by providing European researchers with transnational and/or virtual access to harmonized capacities, unique services, and comprehensive data addressing the current and future needs of public authorities. The EIRENE PPP project brings together leading international experts and institutions to prepare EIRENE RI for implementation.

The preparatory phase will ensure that EIRENE RI reaches the legal, financial, organizational, and technical maturity necessary for its implementation. This phase will primarily involve specifying the national hubs and their members, the composition of the key pillars of the EIRENE RI architecture, topical nodes, and related services. The inventory of available national capacities will be executed, the management structure introduced, and the core facilities, services, and **user access strategies defined**. Considering the strong impact that EIRENE RI is expected to have on the protection of health and on chemical safety, and its high relevance for policy-making and implementation of international treaties, **its stakeholder community** includes major international organizations and agencies. All categories of stakeholders will be represented in the Stakeholders' Forum and the **Users' Forum**.

Users (or stakeholders) represent an essential element of EIRENE RI, especially during the preparatory phase, as this research infrastructure embodies the **concept of Open Science** and integrates previously scattered capacities into an efficient network. The Open Science practices are in the core of EIRENE RI implementation. The infrastructure will provide physical and remote transnational access (TNA) to its facilities (e.g., laboratories) and access to data and services via virtual access (VA). A users' access framework will be designed to provide effective, transparent, tailored, and user-friendly access and thus deliver high-quality services to a broad users' community, including scientists, policymakers, private companies, health providers, NGOs, and citizens. A wide range of customized tools will be needed to accommodate the individual needs of this highly diverse group of users. The preparatory phase will ensure that EIRENE RI reaches the legal, financial, organizational, and technical maturity necessary for the implementation of these tools. This intention materialized by the efforts put into WP4 as formulated in the strategic document of the EIRENE RI-PPP¹.

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 Objectives

For the aim of preparing the EIRENE pilot, we involve the national core facilities with services that are ready to be deployed through EIRENE now as identified in T2.2², set up the access tools, and test the access procedures for both the physical and virtual (TNA) access described in T2.3³. The pilot results are supposed to provide WP2 with feedback on further improvement of the users' access framework in the future development of EIRENE core services. Full execution of the pilot, i.e. real access of external partners to capacities and services of RI, is beyond the scope of this project. This means that such conditions, verifying the functionality of Open Access to the EIRENE capacities and testing the access procedures, will be simulated with EIRENE partners.

1.2. WP4 Deliverables

D4.1 EIRENE RI Access procedures to be tested [M24]

D4.2 EIRENE RI Facilities – report [M24]

D4.3 EIRENE RI Pilot Design and Tools [M35]

1.3. Task T4.2: Definition and preconditions

This task worked with the draft plan for the development of EIRENE RI services and the inventory of core services ready to be offered to the user community delivered in T2.2 of WP2 (*Inventory of existing services and identification of synergies and gaps*).

In the frame of Task T2.2, the pillars of the services were outlined based on the experience of both the EIRENE RI partners and other ESFRI RIs. In the deliverables of WP2, senior scientific staff of Utrecht and Örebro University first identified and described **in total 10 services** in the field of exposure assessment in Europe applying prior information gained in diverse projects (SIRENE, HBM4EU, EURION, EHEN, PARC). They outlined a detailed questionnaire with specific questions regarding the type of services (WP2) and the human resources (WP6). Using this survey, it was possible to evaluate which institutions can offer which of the 10 core services:

² T2.2: *Inventory of existing services and identification of synergies and gaps* (UU, all partners, M1-36)

³ T2.3: *An access to the EIRENE RI services* (CSIC, all partners, M7-24)

Table 1: Pillar structure of the 10 EIRENE core services and their corresponding domains⁴

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 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, 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 cataloging of exposome data (e.g., cohorts, algorithms) Biostatistical and/or bioinformatics tools and platforms for investigating exposome-human health interactions

Furthermore, the WP2 Lead (Utrecht University) developed a sustainable model of EIRENE services classifying them into six pillars (A to F) and dividing them into two categories (Trans-National (physical) and Virtual Access).

Trans-national services cover chemical, toxicological and biological profiling, and can either require a physical infrastructure (measurements in a laboratory), or remote access. Virtual services are comprised of environmental data, human data and tools and require a virtual infrastructure (online tools, platforms and data storage system and repositories). The services defined were integrated in the new EIRENE **pillar structure** (Table 2).

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

Sustainable model of EIRENE services

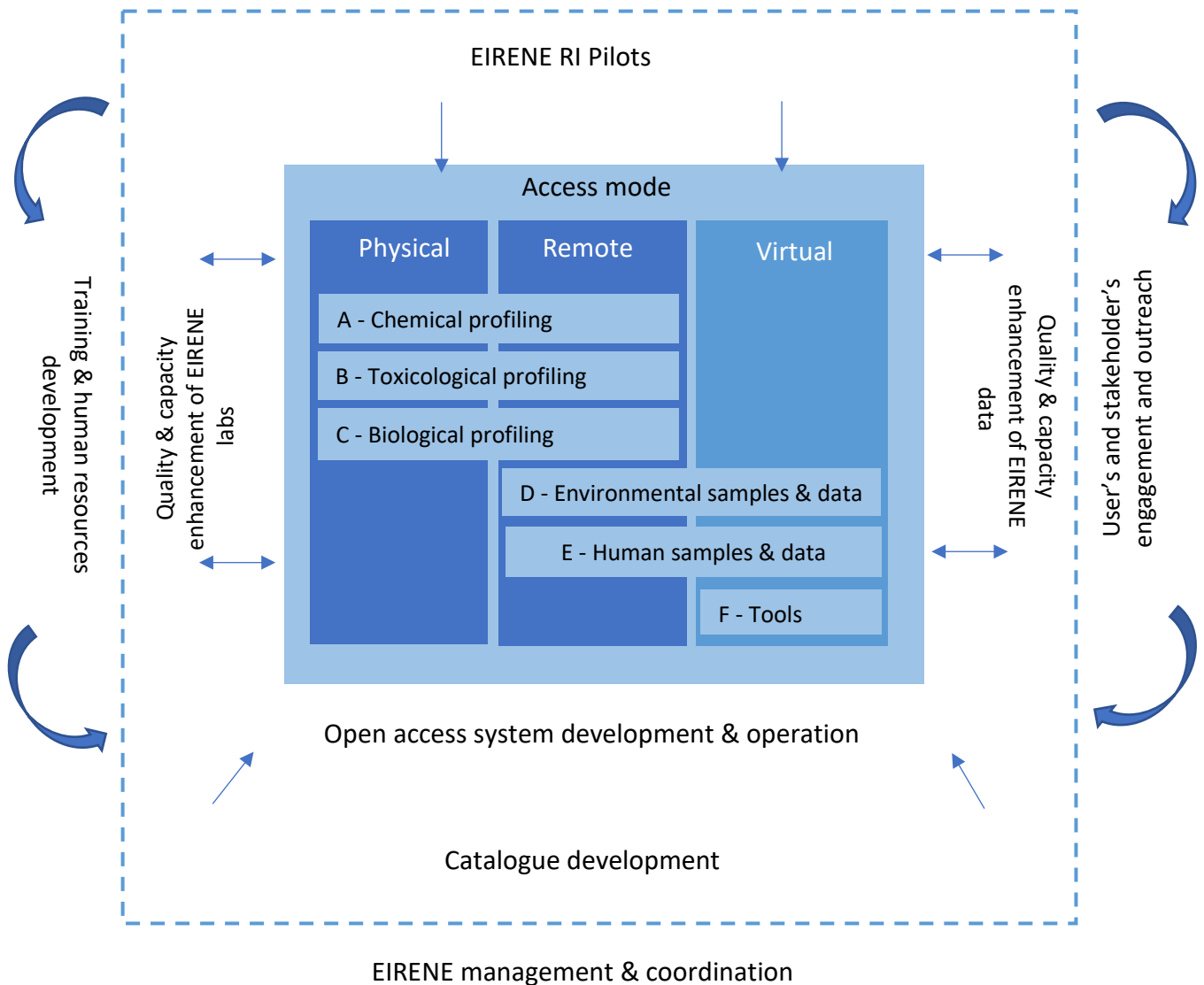


Figure 1. The EIRENE pillar structure includes six distinct pillars (A-F) divided into two categories, the Transnational Access (1) and the Virtual Access (2) to the EIRENE services.

We selected the elements to be tested in the pilot⁵ considering the high complexity of the range of services, i.e. multiple procedure versions for various types of services including access to services of the Head office and the Central Hub (at Masaryk University).

With this background we identified the facilities and services to be tested in the EIRENE RI Pilot. A variety of services in multiple pillars was included for both physical (TNA) and virtual access (VA). Attention was paid to the availability of financial and human resources for the establishment of necessary tools and procedures.

⁵ Such as a presentation of the portfolio of services to potential users, application procedure for access, evaluation of submitted proposals regarding their feasibility, scientific quality, and ethical considerations, access documentation, e.g. contract, feedback and report forms, evaluation of services etc.)

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

In the EIRENE pilot, we involved the **national core facilities with services that are ready to be deployed through EIRENE now.** identified by Utrecht University partners in T2.2. This task aimed to **prepare an inventory of existing services and identify synergies and gaps.** Utrecht used the list of EIRENE RI core services developed in T2.1⁶. Utrecht performed the inventory of services (already provided in the national research infrastructures) and assessed their extent and readiness to be offered via Open Access.⁷

This work provided **input for the analysis of gaps and a draft plan for the development of EIRENE RI services** as the main outcome of this task. The implementation roadmap devised in T1.4 was considered here including proposed quality management schemes and harmonisation criteria. It should inform WP7 (Financial Planning), developing the EIRENE RI financial plan, and WP4 elaborating a design of the EIRENE RI pilot.

2. Identifying the facilities and services to be offered through the EIRENE RI Pilot

A variety of services in multiple pillars for both physical and virtual access are intended to be tested in the pilot. During the survey performed in WP2 and WP6, WP4 initiated to ask, if the service offerings would be available for testing Open Access in the EIRENE pilot. The partners that are open to participating in the pilot are outlined in Table 2 together with the respective service(s) they are offering.

⁶ T2.1: Identification of core services (UU, all partners, M6-18)

⁷ 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.

Table 2: Partners that indicated their interest in participating in the EIRENE pilot and description of the corresponding core services. See Annex 1 to expand the entire table with all the descriptions.

EIRENE partners and their services available for the EIRENE Pilot (WP4)										
10 EIRENE services / Country Code	01. Collecting and providing samples	Describe	02. Access to cohort study or survey data	Describe	03. Measurement of exogenous substances	Describe	04. Omics-based analysis	Describe	05. Quantification/Determination of toxicity	Describe
AT					University of Vienna - Austria 1 (Warth)	Non-targeted	University of Vienna - Austria 1	Type of omi		
AT					University of Vienna - Austria 3 (Warth)	Targeted an				
BE	VITO	VITO has a b			Medical University of Innsbruck - Austria 4	The Core Fa	Medical University of Innsbruck - Austria 4	Type of omi		
BE	Ghent University	Biological s	Ghent University	REHS	VITO	Targeted sus		LC-MS/MS	VITO	VITO can of
BE	KU Leuven	Biobank, Ser		GLORIA-Geo	Ghent University		LC-MS/MS	Metabolom	KU Leuven	In vitro asse
CY	Cyprus University of Technology	Access to th	Cyprus University of Technology	Name of Col	Cyprus University of Technology	write and so	Cyprus University of Technology	GC-MS/MS		
CZ					Masaryk U - Price	LC-HRMS/M	Masaryk U - Price	Quantitativ		
CZ	Masaryk U - Pribyllova	Sampling of			Masaryk U - Pribyllova	Targeted me				
CZ	Masaryk U - Andryskova	The CELSPAC	Masaryk U - Andryskova	CELSPAC: TN			Masaryk U - Linhartova	Type of omi		
DK	Aarhus U	Biobank, Env	Aarhus U	The Danish j			Aarhus U	LC-MS/MS	Aarhus U	1 - Laborato
FR					INSERM - LERES	Type exogen				Models: Hus
D	Leipzig U	Samples are		LIFE Child						
GR	University of the Aegean	Environmen				Type exogen			University of the Aegean	Ecological E
GR	University of Crete (UOC)	Biobank, Ser	University of Crete (UOC)	Athletes Inv	University of Crete (UOC)	*Type exoge	University of Crete (UOC)	Type of omi	University of Crete (UOC)	In vitro/in v
GR	Aristotle University of Thessaloniki	Our Institut	Aristotle University of Thessaloniki	EXPOSE: HB	Aristotle University of Thessaloniki	Type exogen	Aristotle University of Thessaloniki	Type of omi	Aristotle University of Thessaloniki	Toxicity qua
GR	Foundation for Research and Technology	Collection o	Foundation for Research and Technology	Blood Seru	Foundation for Research and Technology	*Screening	Foundation for Research and Technology	*GC-MS an	Foundation for Research and Technology	Reconstruct
GR	Medical School, National and Kapodistri	Past and Pre	Medical School, National and Kapodistri	National Nes						
IT	CNR	*Research-n			CNR	Heavy meta				
IT										
LX	Laboratoire national de santé du Luxembo	Environmen			Laboratoire national de santé du Luxembo	Targeted an				
LX	LIST	We sample	LIST	DEMOCOPH	LIST	Drugs, illicit			LIST	In vitro lung
NO	NIPH	Access to th	NIPH	The New	NIPH	LC and GC-r				
SI					PhIME; HEA					
SI	Jožef Stefan Institute	We are desi			Jožef Stefan Institute	targeted: tra				
SI			University of Ljubljana, Faculty of Medic	Children (7 y			National Institute of Biology	Type of omi	National Institute of Biology	1.) In vitro a
SI										
SE	Swedish University of Agricultural Science	Sampling of			University of Ljubljana, Faculty of Pharm	Screening of	University of Ljubljana, Faculty of Pharm	LC-MS/MS	University of Ljubljana, Faculty of Pharm	In vitro cell
SE					Swedish University of Agricultural Science	Effect-direct			Swedish University of Agricultural Science	Effect-based
SE					Örebro University-Victor Castro-Alves	Non-target	Örebro University-Victor Castro-Alves	a) Metabol	Örebro University-Victor Castro-Alves	In vitro a) j
SE					Örebro University-Anna Kärman	Targeted S/L			Örebro University-Anna Kärman	In-vivo mod
SE	Stockholm University / Science for Life	Access to th			Stockholm University / Science for Life	LSU/ACES dir			Stockholm University / Science for Life	In vivo mod
SE										
SE					Karolinska Institutet-Craig Wheelock	Type of exo	Karolinska Institutet-Craig Wheelock	Type of omi		
NL	KWR Water Research Institute	Sampling of			Vrije Universiteit Amsterdam	Type exogen	Vrije Universiteit Amsterdam	LC-MS/MS	Vrije Universiteit Amsterdam	In vitro asse
NL					KWR Water Research Institute	https://www			KWR Water Research Institute	https://www
NL					Wageningen Food Safety Research (WFS	Type exogen			Wageningen Food Safety Research (WFS	Our Institut
NL			Utrecht University	PIAMA; AMI	Utrecht University	Consultatio				
NL					Leiden University	Combinator	Leiden University	Type of omi		

10 EIRENE services / Country Code	06. Biostatistical and/or bioinformatics tools and platforms	Describe	07. Databases and exposure maps on environmental factor	Describe	08. FAIR cataloging of exposure data	Describe	09. Training	Describe	10. Additional Services	Describe
AT							University of Vienna - Austria 1	Training typ	University of Vienna - Benedikt Warth	Advanced/c
AT										
BE	VITO	Exposure of	VITO	Terrascop	VITO	FAIR Data H				Modelling e
BE	Ghent University	R- and Pyth	Ghent University	GLORIA is v	Ghent University	Data manag				We provide
BE							KU Leuven	Training typ		
CY	Cyprus University of Technology	Harmonizat						Training typ		
CZ	Masaryk U - Damborsky	FAIR storage	Masaryk U - Damborsky	Effect of mu			Masaryk U - Damborsky	Training typ		
CZ	Masaryk U - Price	Galaxy tools					Masaryk U - Price	Training typ		
CZ							Masaryk U - Pribyllova	Training typ		
CZ										
CZ	Masaryk U - Blaha	DATA INTEG								
DK			Aarhus U	Data Bases:						
FR	INSERM - LERES	Bioinforma						Inserm/Inser	Hands-on training in expos	Training typ
D										
GR	University of Crete (UOC)	Include desc							University of the Aegean	Training typ
GR	Aristotle University of Thessaloniki	Agilent's Ge	Aristotle University of Thessaloniki	*Type of em	Aristotle University of Thessaloniki	*Wearable	Aristotle University of Thessaloniki	Training typ	Aristotle University of Thessaloniki	PBPk and a
GR	Foundation for Research and Technology	standardize	Foundation for Research and Technology	Hydrogeoch			Foundation for Research and Technology	Training typ	Foundation for Research and Technology	Modeling of
GR										
IT			Italian Space Agency	Access to da						
LX									LIST	Training typ
NO	NIPH	Bioinforma			NIPH	Chemical ex				
SI	Kemijski inštitut/National Institute of Chem	numerical re							Jožef Stefan Institute	Training typ
SI	Jožef Stefan Institute	We are traini	Jožef Stefan Institute	GIS, Sloveni					National Institute of Biology	Training typ
SI			University of Ljubljana, Faculty of Medicine	air pollutio						
SI	Jožef Stefan Institute	We analyze			Jožef Stefan Institute	We are and	Jožef Stefan Institute - Dzeroski	Training typ		
SE							University of Ljubljana, Faculty of Pharm	Training typ		
SE	Örebro University-Victor Castro-Alves	Advanced bi					Swedish University of Agricultural Scien	Training typ		
SE							Örebro University - Castro-Alves	Training typ		
SE										
SE	Karolinska Institutet-Roxana Merino Marti	Human Expc					Stockholm University / Science for Life	Training typ		
SE							Karolinska Institutet	Training typ		
NL	Vrije Universiteit Amsterdam	Highly capab	Vrije Universiteit Amsterdam	Geo-spatial					Vrije Universiteit Amsterdam	High throug
NL	KWR Water Research Institute	https://www					KWR Water Research Institute	Workshops	KWR Water Research Institute	Additional s
NL										
NL			Utrecht University	Exposome d	Utrecht University	Data manag	Utrecht University	MSc in Envir		
NL										

For identifying the national nodes that are ready to deploy and offer the selected services, attention was given to the availability of financial and political support of the respective national node and human resources for the establishment of necessary tools and procedures.

2. Selection of facilities and services to be tested in the pilot

The selection of facilities and services for the pilot was thoroughly discussed, both internally and during regular consortium management board meetings. From these discussions, two potential approaches emerged that can be taken in the next stage:

- (1) **Detailed Approach:** This option involves testing access to each of the 10 selected EIRENE services across all six main pillars, with a different volunteer facility for each service. This would provide a **comprehensive and detailed simulation** of the full range of available services and providers.
- (2) **Targeted (Selective) Approach:** Alternatively, a **more focused pilot** could select two key services from two pillars (A and D)⁸ and test access through a few of providers-volunteers. This approach simplifies the pilot, concentrating on two core services related to toxic chemicals, while still ensuring diverse feedback. This method would streamline the process, allowing for a **targeted, efficient evaluation** of the key services central to EIRENE's mission.

The main challenge of this step will be ensuring that the facilities are fully prepared to deliver the services they reported during the initial survey conducted by the University of Utrecht as part of Task 2.2 (Inventory of Existing Services).

Given the understandable limitations of accuracy in this first survey—due to the large number of institutions involved and the wide diversity in the nature and scope of their services—it is anticipated that a **full-scale pilot execution would be more feasible after the second round of the inventory in fall 2024**, which will focus on verifying and assessing the readiness to deploy services (collected in the Qualtrics survey in 2023).

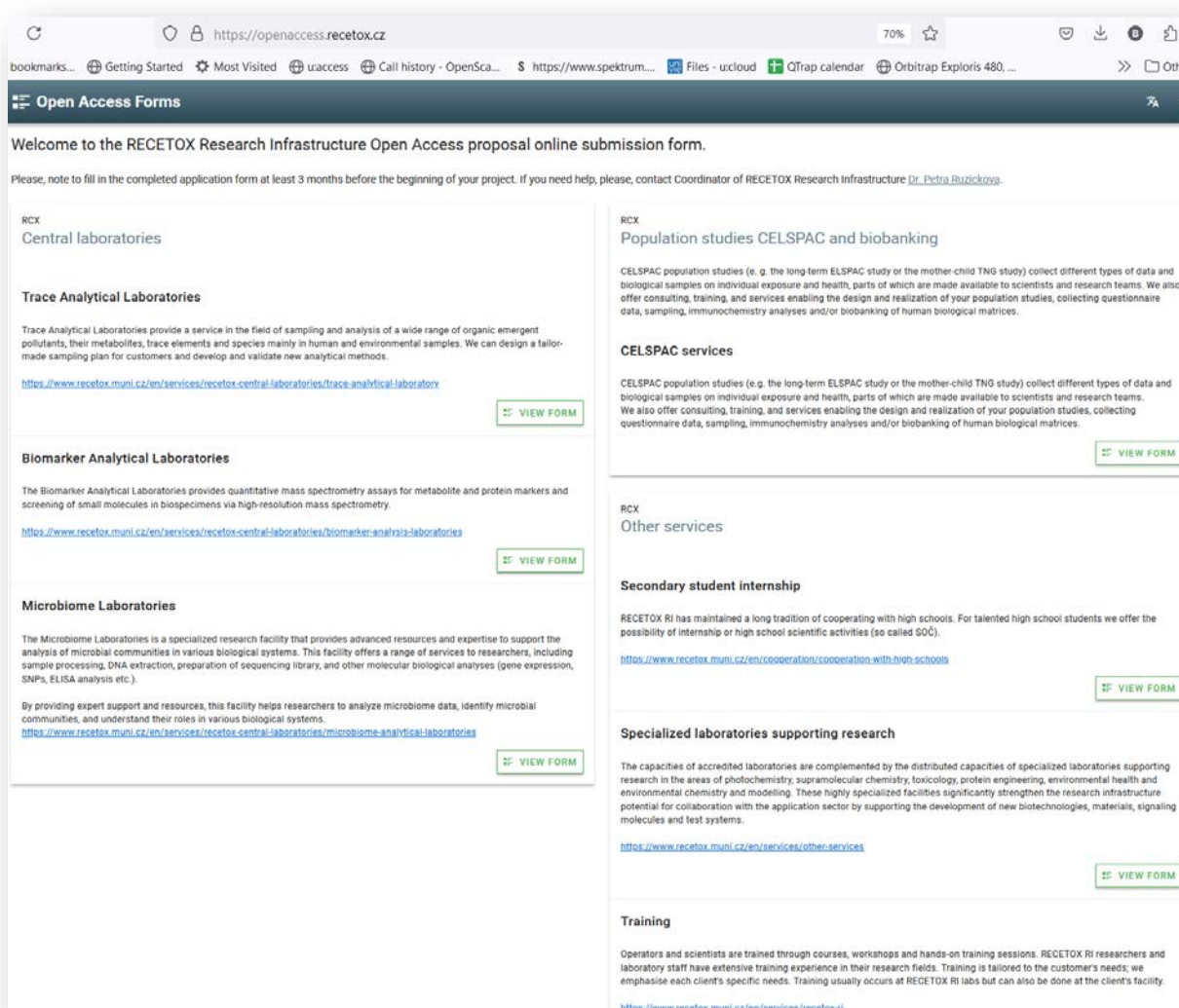
⁸ A - Chemical profiling, D - Environmental samples & data.

3. 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 leads of Czechia and the Netherlands and their teams.

4. ANNEXES

Annex 1 Description of CZ national node access point and procedures



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

