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FREIE UNIVERSITÄT

# GUIDE-IT

**Guide** to Data Sharing of **I**maging **T**rials

Proceedings of the Klausurtagung / Colloquium
11th December 2024

# Editorial

## Breaking Barriers in Clinical Imaging Data Sharing
## Insights from the GUIDE-IT Colloquium, December 11th 2024

The recent scientific colloquium (Klausurtagung) of the GUIDE-IT project provided a critical platform for discussing transformative strategies in clinical imaging data sharing. Anchored in the FAIR guiding principles—findability, accessibility, interoperability, and reusability—the discussions shed light on five pivotal challenges that must be addressed to harness the full potential of clinical imaging data.

1. **Stakeholder Acceptance**: The promise of improved medical care through image sharing is undeniable. However, gaining the trust of key stakeholders, including patients, clinicians, institutions, and policymakers, is essential. Addressing concerns such as data security, privacy, and the equitable distribution of benefits is foundational to achieving widespread acceptance.

2. **Use and Access**: Cultural shifts in the medical imaging community indicate a growing openness to data sharing. Yet, the implicit risks of re-identification and intellectual property complexities remain significant barriers. The colloquium emphasized the need for robust anonymization methods and clear guidelines for fair use.

3. **Data Quality**: The usefulness of shared imaging data hinges on its quality. Standardized metadata, capturing critical parameters of image acquisition and interpretation, was highlighted as a prerequisite for meaningful data reuse with a special focus on established standards, such as DICOM. Collaborative efforts to define these standards are urgently needed.

4. **IT Resources**: The vast and diverse nature of imaging datasets presents logistical challenges. From the need for expansive storage solutions to the computational demands of data analysis, the colloquium underscored the importance of investing in scalable IT infrastructure tailored to imaging data.

5. **Sustainability**: The establishment of a economically viable data sharing ecosystem requires long-term vision. Beyond initial investments, the GUIDE-IT project aims to create a sustainable academic infrastructure that can adapt and evolve, ensuring ongoing value for the scientific community and society at large. Therefore, the colloquium focused on critical aspects, such as responsibilities and the institutionalization of the GUIDE-IT project beyond the initial project.

The GUIDE-IT colloquium underscored that the challenges of clinical trial imaging data sharing are not insurmountable but require a concerted, multidisciplinary approach. By addressing these five challenges, the project is paving the way for a future where data sharing is transformative for medical research and patient care.
This report focuses on the methodologies, frameworks, and innovative solutions proposed to address the identified challenges in clinical trial data sharing. It will highlight critical advancements in stakeholder engagement strategies, technical infrastructure development, and sustainable practices discussed during the event.

Berlin, January 2025

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**Tim Kilgus**, Freie Universität Berlin & Charité Universitätsmedizin Berlin

# 1. Agenda

The GUIDE-IT Colloquium was held online via videoconference to enable the participation of researchers and experts worldwide. The event was structured as follows:

**14:00 - 14:05 (CET)** Welcome Prof. Marc Dewey, Prof. Dagmar Krefting, Prof. Felix Balzer, Prof. Martin Gersch & Prof. Daniel Fürstenau

**14:05 - 14:13 (CET)** Network / Organization (Dr. Melanie Bosserdt)

**14:13 - 14:28 (CET)** GUIDE-IT Pilot and Pilot study (Bernhard Föllmer, James Bowden)

**14:28 - 14:33 (CET)** Data Quality and Interoperability (Dr. Elias Grünewald)

**14:33 - 14:40 (CET)** Economic Sustainability (Prof. Daniel Fürstenau)

**14:40 - 14:45 (CET)** From Pilot study to Full-Scale Platform Realization (Prof. Marc Dewey)

**14:45 - 15:00 (CET)** Discussion and critical GUIDE-IT friend's review (Prof. Marc Dewey & Prof. Martin Gersch

# 2. Project overview

The GUIDE-IT project highlighted its collaborative network, learning from national, European and international initiatives. A systematic review identified data-sharing practices in medical imaging trials, emphasizing opportunities for secondary data use and quality assurance.

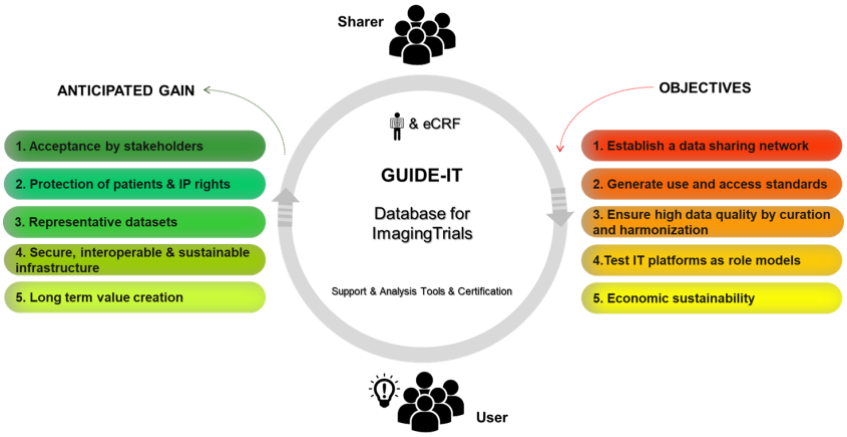


*Figure 1. Project overview*

One example of the results of the pre-project includes the successful creation of legally compliant Data Transfer Agreement to include data from the SCOT-HEART and DISCHARGE trials as a collaborative effort between the University of Edinburgh and Charité Universitätmedizin Berlin. This immense effort, backed by the legal departments of both organizations, allows to effectively share medical imaging trial data even across European and UK legislative frameworks in compliance with the EU General Data Protection Regulation (GDPR) and provides a blueprint for cross-border data sharing and serves as a template for further collaborations with other organizations in the GUIDE-IT data sharing network.


*Figure 2. Cross-institutional Data Transfer Agreement*

# 3. Network and organization

The GUIDE-IT team's has a strong commitment to enrich engagement with a broad network of national, European, and international experts and initiatives. This approach allows the project to benefit from the wealth of knowledge and experience accumulated by leaders in the medical imaging and data-sharing domains.

By learning from the successes and challenges faced by other initiatives across borders, GUIDE-IT refines its strategies, ensuring that it remains at the forefront of innovations in medical imaging data sharing. This collaborative model fosters a deeper understanding of best practices, aligns the project with international standards, and accelerates the development of robust, interoperable infrastructures for sharing clinical imaging data.

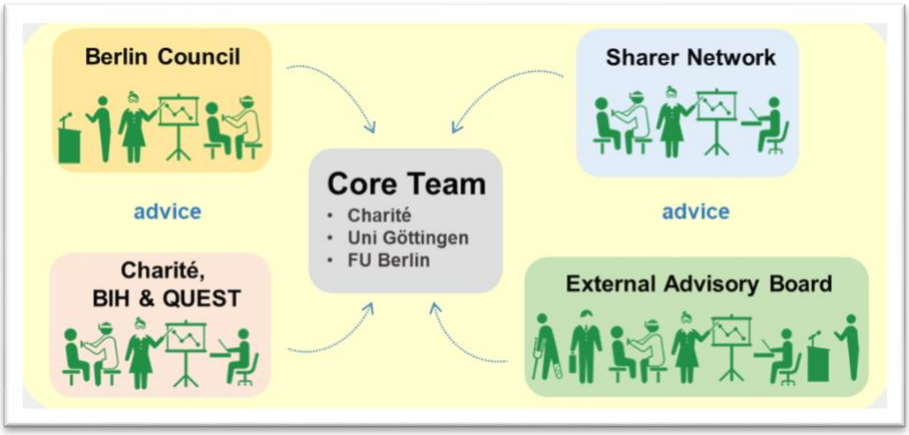


*Figure 3. Governance structure.*

We are happy to have the following strong partners in our network and our governance structure. Throughout more than ten online videoconferences with other initiatives, among other expert consultations, the GUIDE-IT team has constantly identified challenges ahead and solutions that enable the data sharing of clinical imaging trials.


*Figure 4. Networking partners*

# 4. Community engagement

At the GUIDE-IT colloquium, we used an Mentimeter to foster interactive collaboration among participants. This real-time polling and feedback platform allowed attendees to contribute their thoughts and perspectives instantly, enhancing the overall engagement of the event. Through this tool, the project team was able to gather valuable insights and feedback on key challenges, such as data sharing barriers, stakeholder concerns, and IT infrastructure requirements.

Participants could respond to questions, vote on proposed solutions, and engage in the discussion, creating a dynamic and participatory environment. The platform's ease of use ensured that all voices, whether from clinicians, data scientists, or policy experts, were considered. This collaborative effort highlighted shared priorities for advancing the GUIDE-IT project in the full project (under review).

Below some example community engagement results are listed.

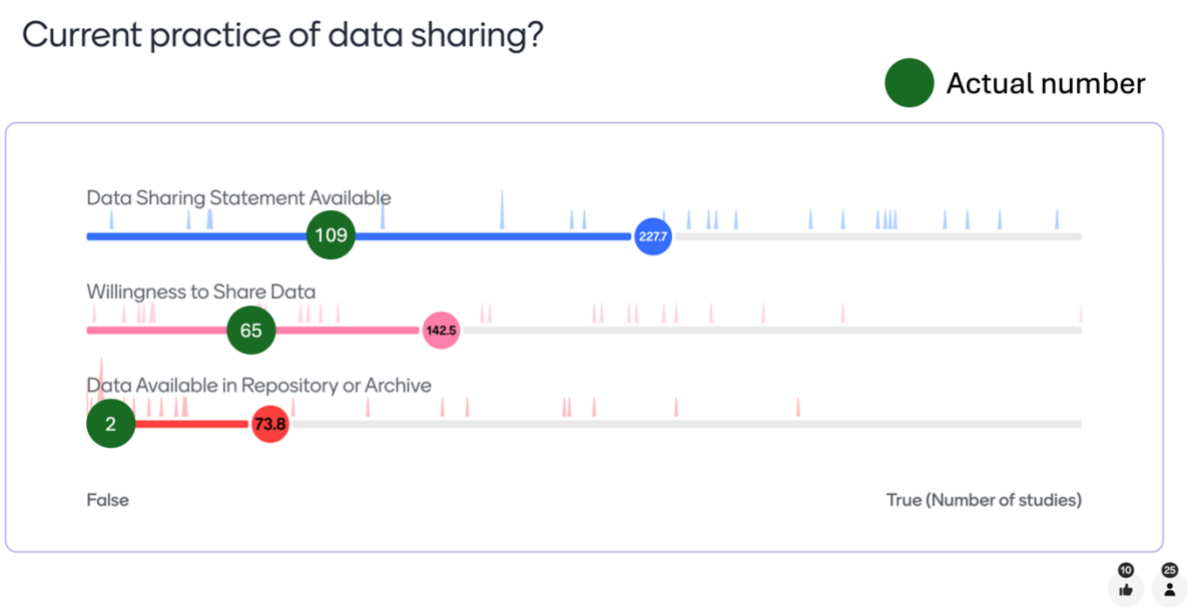


*Figure 5. We asked community experts on their estimation of FAIR data sharing practices. Interestingly the experts overestimated the availability of good scientfic practice publications and the availability of data sharing statements, the willingness to share data, and the data availability on a data sharing platform. Hence, the need for the GUIDE-IT platform is once again underlined.*

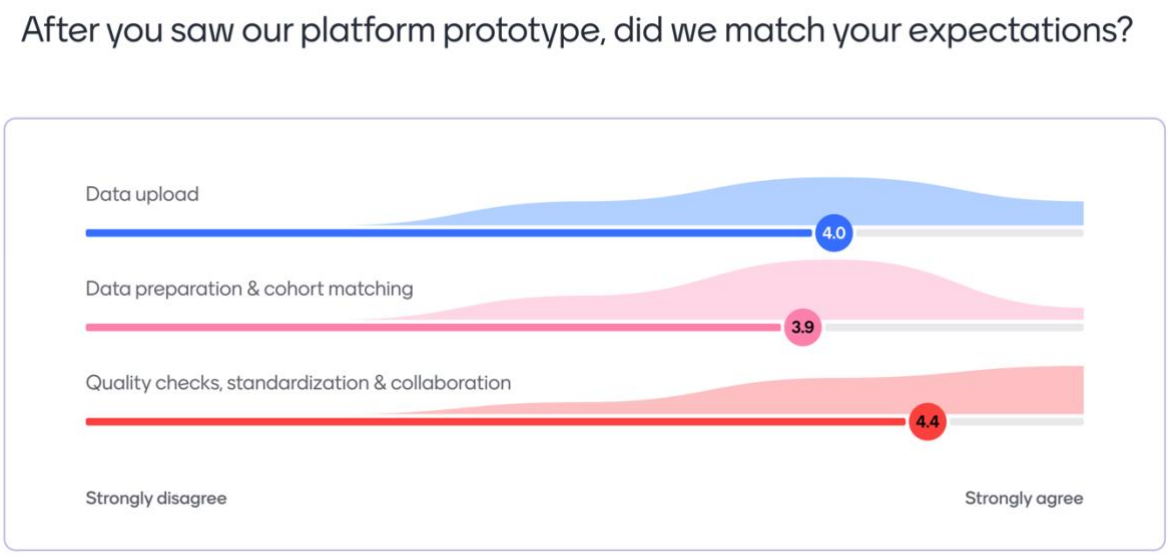


*Figure 6. After we provided a live technical demonstration of our platform prototype, we asked the community on their expectations. The results show that the community strongly agrees that the platform will positively influence the medical imaging trial practice.*

Furthermore, we asked the audience on aspects to be put on the research agenda within the potential full-project phase. Among the most listed answers are:

- Networking functionalities
- Onboarding of a critical number of datasets
- Testing end-user workflows and comparisons with other platforms
- AI testing integration
- Interfaces for testing models
- Exhaustive meta-data quality reports

and many others.

These results highlight, that the GUIDE-IT platform has developed a feasible prototype to share imaging data across several institutions and further raised awareness within the imaging trial community regarding the availability of data sharing statements. This is important, since the full implementation of the project aims to scale the platform to facilitate global sharing of randomized imaging trial data.

# 5. Platform Prototype and Data Quality

As part of the scientific colloquium, the GUIDE-IT team provided insights into the platform prototype and measures to improve data quality across different clinical trials. To do so, the team provided an overview on the process associated with the use of the platform prototype, showcased the current state of the prototype, and further presented tools to assess data quality.

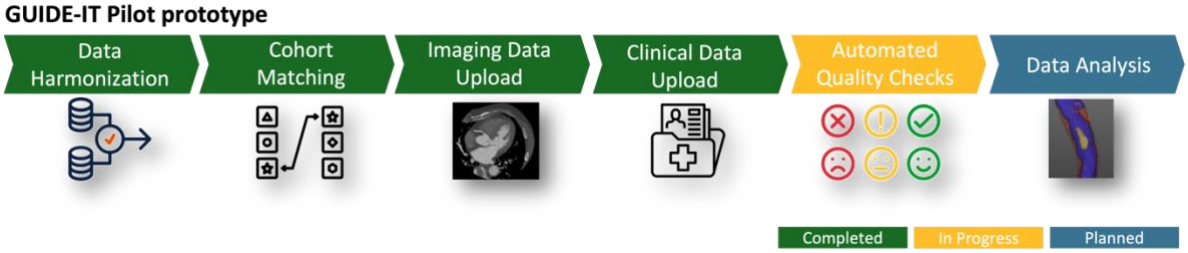


*Figure 7 Process description of the GUIDE-IT prototype*

For the process of the GUIDE-IT prototype, the Data Harmonization, Cohort Matching, Imaging Data Upload, and Clinical Data Upload have been successfully implemented. During the independent analysis of the DISCHARGE and SCOT-HEART trial, the functionalities have been tested thoroughly, and major updates been conducted. In the current state, the automated quality checks are still in progress. Data analysis has not been integrated in the platform prototype yet.
For data quality checks, initial knowledge-graph based approaches have been developed and the implementation will be approached in the upcoming months.

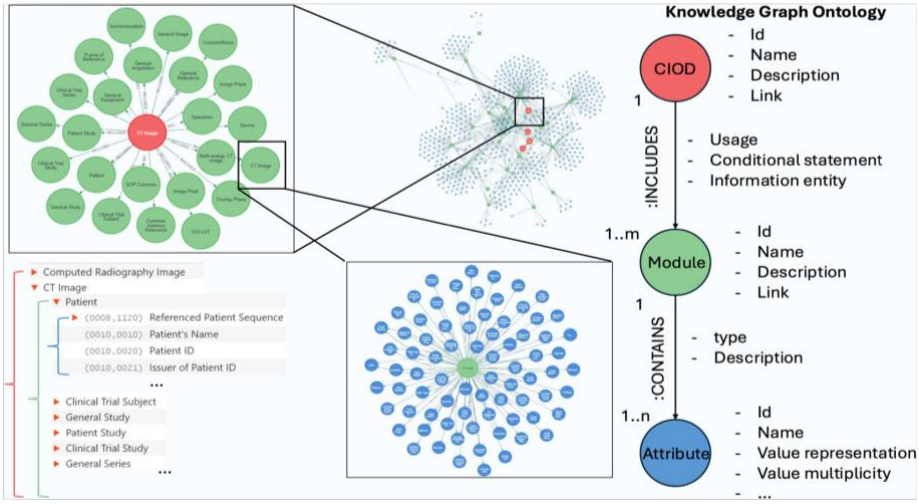


*Figure 8 Knowledge graph to assess meta-data quality*

During the scientific colloquium, the GUIDE-IT team presented the current state of the prototype by highlighting the individual process steps. The following figure showcases the data dashboard with demo data of the DISCHARGE trial.

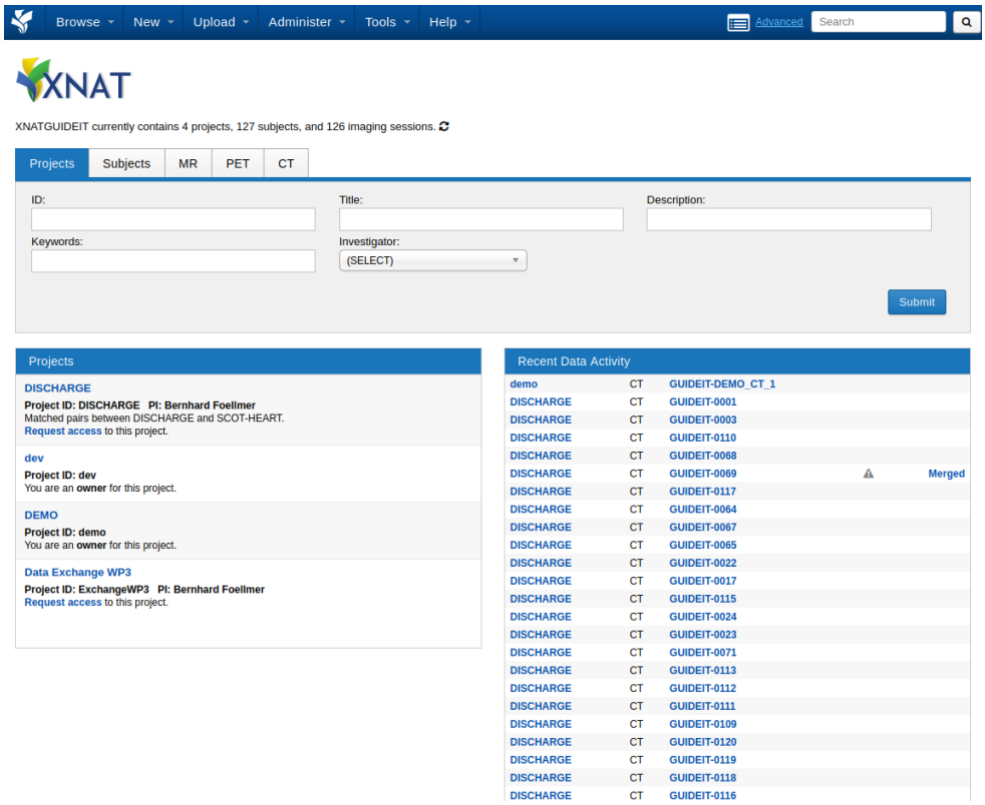


*Figure 9 Platform prototype*

The presentation of the artefacts and the critical evaluation of the participants clearly highlight, that the data sharing community has a strong feeling that their needs are addressed by the GUIDE-IT team.

# 6. Economic Sustainability

The GUIDE-IT team aims to create a long-term viable research infrastructure. The fore, it aims to establish an institution beyond the project scope that provides clear responsibility structures with non-profit objectives. Achieving this goal is integral part of the GUIDE-IT project.

Therefore, the team has presented its plans within and beyond the GUIDE-IT project funded by the German Research Foundation. As part of that, the project team has presented its preliminary plan to establish a economically sustainable organization, learning from national, European and international examples, that contributes to the Open Science endeavor.

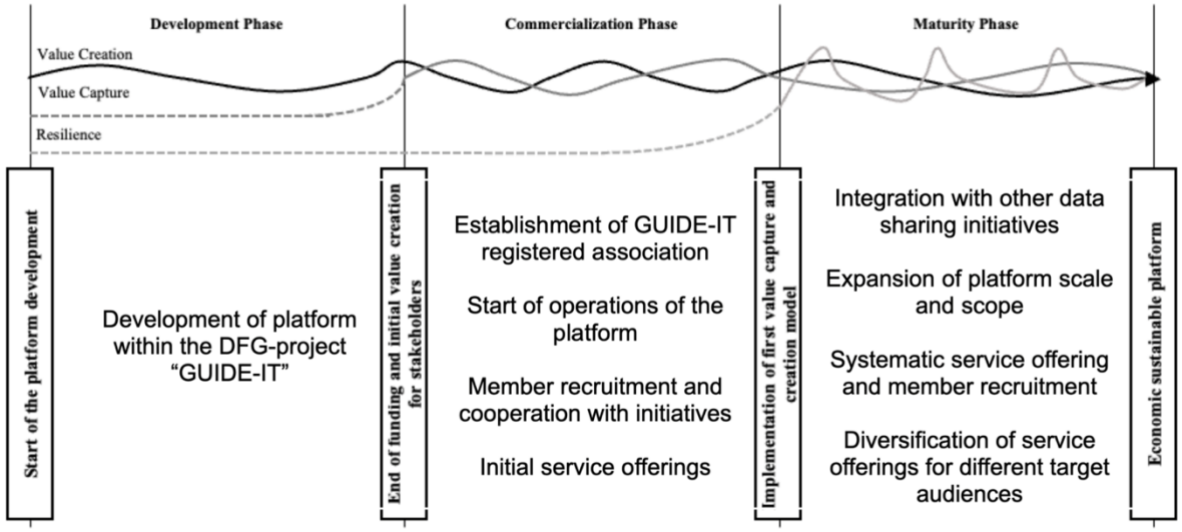


*Figure 10 Preliminary plan for the economic sustainability of the GUIDE-IT project*

# 7. Outlook

The GUIDE-IT pre-project will terminate in April 2025 and will transition towards the proposed full-project after a evaluation by German Research Foundation. As part of the application for the full-project, the GUIDE-IT team has decided to consolidate and integrate its efforts in the upcoming years with a strong focus on close cooperation internally, but also with an increased outreach to existing and new partners.

A key role in that transition plays the transformation of the five working packages into three Key Areas as illustrated in the following graph.

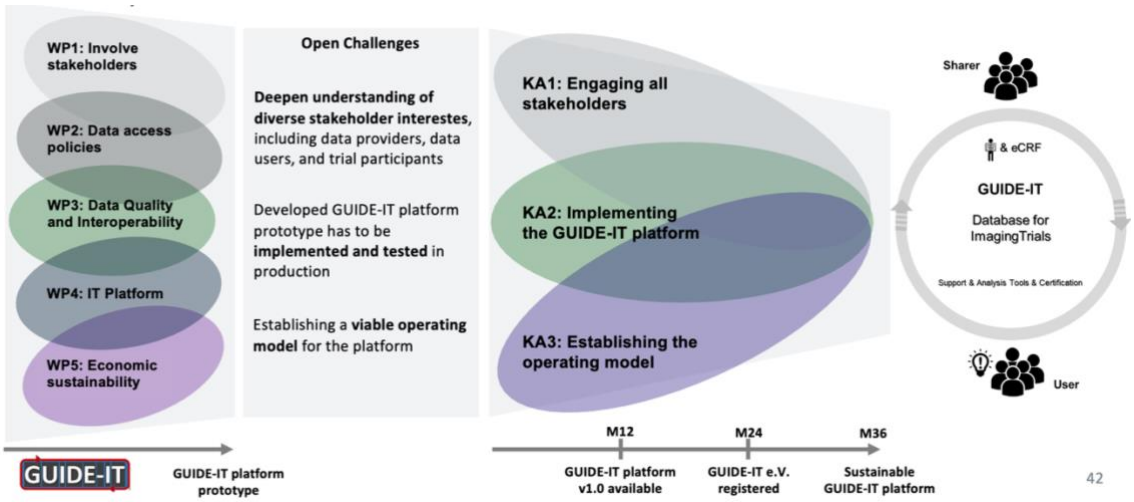


*Figure 11 Transformation of the Working Packages into Key Areas*