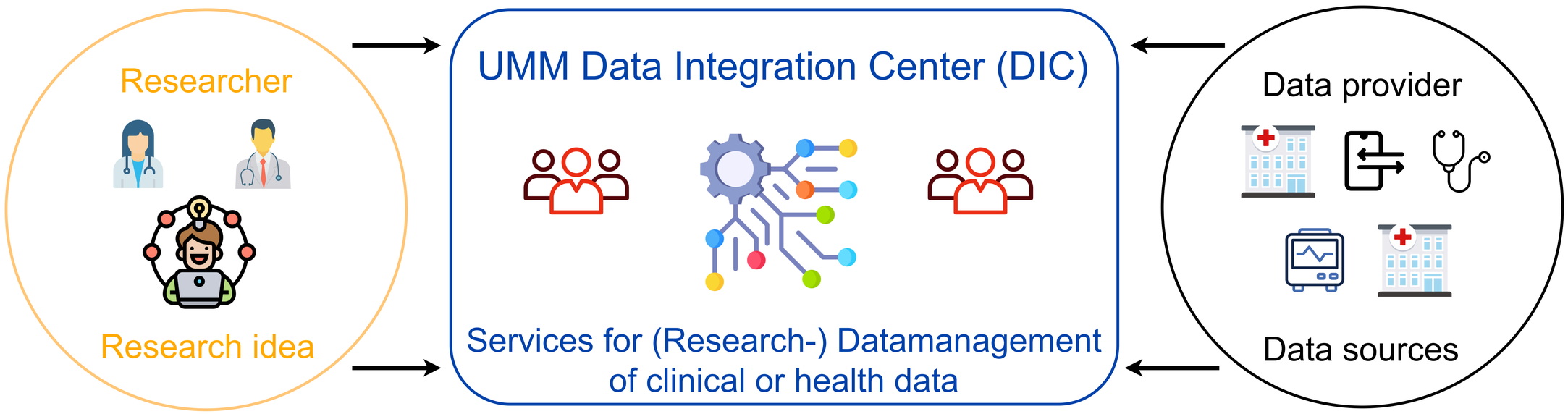
# Clinical Research Data Management in the UMM Data Integration Center

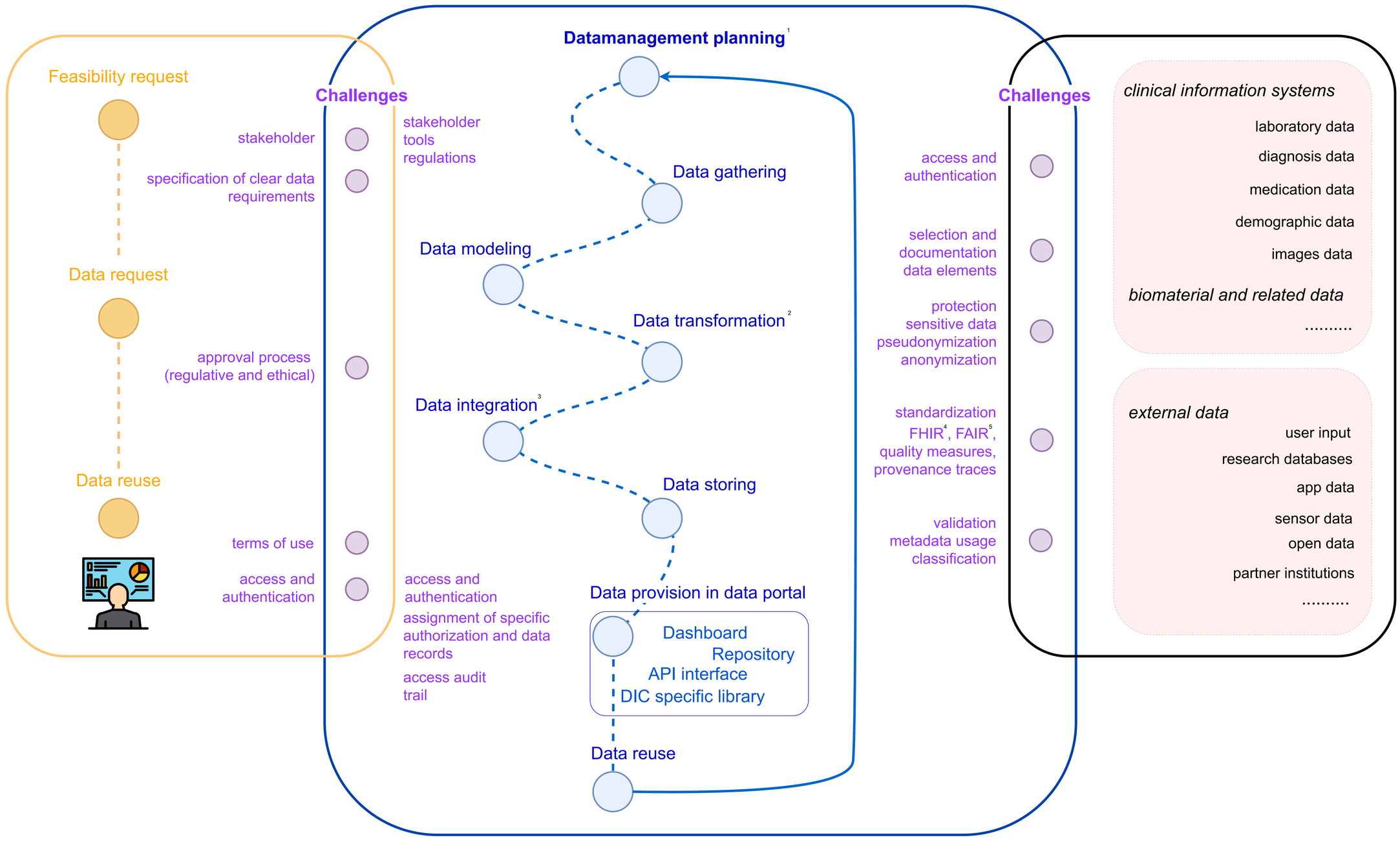
Authors: Gierend, Kerstin - Herzog, Melanie - Hetjens, Michael - Langhals, Martina - Männle, David
Affiliation: Department of Biomedical Informatics, Mannheim Institute for intelligent Systems in Medicine, Medical Faculty Mannheim, Heidelberg University, Mannheim, Germany

**Abstract.** Clinical Research Data Management (CRDM) is a critical component in the operations of Medical Data Integration Centers (DICs), which are designed to consolidate and standardize diverse clinical routine data for improved accessibility and utility. This abstract illustrates the core processes, indicates the tool usage, challenges, and significance of CRDM in the context of DICs. In addition, we emphasize its impact on enhancing the quality and efficiency of clinical research, and the related data sharing.




The primary goal is to support researchers through data management planning, systematic data collection, organization, integration, storing, analysis and archiving of their clinical research data.

Our DIC not only consolidates data from clinical routine systems or biobank but also from various clinical studies. Standardizing these heterogeneous data types into an interoperable data format is essential for enabling meaningful cross-study and -clinical comparisons and meta-analyses, which are foundational to evidence-based medicine.




Given the sensitive nature of clinical (research) data, DICs and researchers must adhere to strict regulatory requirements, such as the General Data Protection Regulation (GDPR). We provide an insight into anonymization of patient data and implementing secure access controls which are necessary to protect patients data privacy and maintain trust in clinical research.

In conclusion, our data managing activities are essential for advancing medical research sharing. We address challenges related to standardization, interoperability, privacy and governance. This enables DICs and researchers to significantly enhance the quality and impact of their research, while contributing to improved healthcare outcomes.

## References:

[1] Gierend K, Freiesleben S, Kadioglu D, Siegel F, Ganslandt T, Waltemath D. The Status of Data Management Practices Across German Medical Data Integration Centers: Mixed Methods Study. J Med Internet Res 2023;25:e48809.
URL: https://www.jmir.org/2023/1/e48809. DOI: 10.2196/48809
[2] Henke E, Peng Y, Reinecke I, Zoch M, Sedlmayr M, Bathelt F. An Extract-Transform-Load Process Design for the Incremental Loading of German Real-World Data Based on FHIR and OMOP CDM: Algorithm Development and Validation. JMIR Med Inform. 2023 Aug 21;11:e47310.
doi: 10.2196/47310. PMID: 37621207; PMCID: PMC10466444.
[3] Kapsner LA, Kampf MO, Seuchter SA, Kamdje-Wabo G, Gradinger T, Ganslandt T, Mate S, Gruendner J, Kraska D, Prokosch HU. Moving Towards an EHR Data Quality Framework: The MIRACUM Approach. Stud Health Technol Inform. 2019 Sep 3;267:247-253.
doi: 10.3233/SHTI190834. PMID: 31483279.
[4] Fast Healthcare Interoperability Resources: https://fhir.org/
[5] FAIR (findable - accessible - interoperable - reusable): https://www.go-fair.org/fair-principles/

All icons from www.flaticon.com: Hospital icons created by Freepik - Flaticon; Hrm icons created by IYIKON Flaticon; Complex icons created by Dewi Sari - Flaticon; Dashboard icons created by xnimrodx - Flaticon; Physician icons created by nawicon - Flaticon; Physician icons created by DinosoftLabs - Flaticon; Bandwidth icons created by orvipixel - Flaticon; ECG monitor icons created by Ahmad Yafie - Flaticon
Thanks to Marina Männle for support on poster creation.