Advancing Sleep Research through Dynamic Consent and Trustee-Based Medical Data Processing

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***Abstract*—Medical data obtained from individual sleep studies are of great value for scientific research. Yet in Germany, their use is often hindered by legal restrictions, problems with heterogeneous data landscape, and lack of standardized data formats and quality criteria. In this paper, we propose a pioneering architecture to remove these barriers. Our distributed setup ensures that sensitive data remains within the secure boundaries of the originating institutions while patients have control over the subsequent use of their anonymized data. At the heart of our approach is the concept of a data trustee, providing easy-to-use interfaces for the key stakeholders: data producers (sleep clinics), data recipients (researchers), and data providers (patients). We use the innovative concept of dynamic consent to update usage rights and conditions. By using containerized data processing and automated de-authentication, data usage requests are filtered through standardized metadata criteria across all connected data producers, ensuring both privacy protection and streamlined data selection. In addition, our system features tamper-proof logging to ensure transparency and traceability across all transactions. With this integrated approach, we aim to realize the full potential of sleep research while adhering to strict privacy standards and enabling seamless collaboration between stakeholders.**

***Index Terms*—data sharing; consent management; secondary use; health data; clinical data management; user interface design; sleep research; data trustee; software architecture.**

I. Introduction

Research in the field of sleep medicine plays a vital role in maintaining and improving human health. Given the complexity of sleep and its impact on numerous aspects of human well-being, the exchange of data collected during clinical standard patient care is crucial, especially for analyzing sleep disorders that occur infrequently. At present, the exchange of sleep research data in Germany is often affected by fragmentation, institutional data silos, bureaucratic barriers, missing transparency, inefficiency, and data quality issues [1]. Research institutions and clinics have a variety of data sources and formats that make it difficult to use and share this data effectively. This leads to a suboptimal use of available resources and hinders progress in sleep medicine as a whole. Consequently, there are several initiatives [2] [3] and research endeavors in Germany aimed at addressing these challenges that currently do not consider the context of sleep medicine. International efforts are underway in sleep research, with databases like SIESTA [4], PhysioNet [5], and the National Sleep Research Resource (NSRR) [6] offering access to polysomnography data, albeit with variations in accessibility, topicality, and usability. While SIESTA is not publicly accessible, PhysioNet and NSRR are curated and freely available but vary in usability, needing clarification case by case. No openly accessible databases are known from Europe.

In this regard, data trust models [7] are a promising solution that enables the secure exchange and secondary use of clinical research data. By introducing trustee entities that act as trustworthy intermediaries between patients, clinics, research institutions, and other stakeholders, privacy concerns can be addressed, and access to sensitive data can be improved across institutions. Trustee models not only provide a framework for secure and privacy-preserving data sharing but also potentially promote transparency and fairness in the handling of medical research data.

Despite the potential of data trust models, various challenges remain in practice. These include issues relating to the self-determined handling of patient data, data security and integrity, compliance with legal regulations, such as the General Data Protection Regulation (GDPR) [8], and promoting trust and collaboration between the stakeholders involved. Patients, research institutions, clinics, and trustees must work together to overcome these cross-organizational challenges and ensure sleep medicine research data's effective and ethical use.

In this paper, we present a digital trustee model architecture for a dynamic, patient-centered sharing of medical sleep research data that contributes to the meaningful secondary use of this data and the establishment of data donation cycles [9]. Our

architecture addresses various challenges and stakeholders' perspectives, lessons learned in the conceptualization and prototypical implementation of such a trustee architecture, and insights into how data trustee models can support data sharing in sleep research. By taking a holistic view of these topics, we hope to provide insights that contribute to developing effective strategies, processes, and information technology (IT) systems to improve data sharing in sleep medicine.

Section II outlines the methodology for designing, implementing, and assessing a trustee platform for sleep research in Germany. Following this, Section III explains the platform's architecture, dynamic consent procedure, and researcher interactions. Section IV covers the evaluation approach and findings, concluding with a discussion on their implications in Section V.

II. Methodology

An interdisciplinary approach was adopted to devise a robust data trust model for the secure management and effective utilization of medical data in German sleep research. Collaborating with clinical personnel, IT specialists, researchers, data protection officers, and ethicists, a comprehensive concept was formulated and iteratively refined. This concept prioritized offering patients and researchers a user-friendly platform that could integrate into existing clinical workflows while ensuring strong data protection measures.

Initial interactive user interface (UI) mockups were developed for patients and researchers in the subsequent phase. These mockups were subjected to evaluation by a small cohort of patients and researchers, assessing trustworthiness, usability, functionality, and aesthetics through a structured questionnaire. The insights gained from this initial evaluation were crucial in shaping the development of a functional prototype. The prototype underwent further scrutiny and refinement, culminating in its presentation to patients, researchers, and domain experts. Utilizing identical questionnaires, the final evaluation aimed to establish comparability between the initial interactive mockups and the fully realized data trustee prototype.

This iterative methodology, integrating stakeholder feedback at various stages of development, ensured the alignment of the final prototype with the envisioned objectives of usability, trust, clinical integration, and data protection.

III. Technical concept and design

A. A distributed architecture for data trustees

Two significant challenges faced in crafting an architecture for a data trust system within the realm of sleep medicine are:

- **Liability concerns:** Given the sensitive nature of patient data, complying with strict legal regulations for handling patient data is a daunting hurdle for clinics in Germany. Direct disclosure of or access to data by third parties is a major challenge due to legal restrictions and liability concerns.
- **Rule enforcement:** Practical monitoring of data protection and data trustee compliance in research projects is a major challenge for trustees. Patients and clinics need a solid level of protection to have confidence in the trustee, even if the data is anonymized.

A monolithic architecture in which medical data is kept centralized and passed on directly to research projects, even with patient consent, proved to be incompatible with these requirements. In our work, we opted for a decentralized, distributed trustee system architecture, as depicted in Figure 1. The architecture follows the C4 model notation [10], focussing only on essential system components for clarity.

We identified four key stakeholders within our trust system: data providers (patients), data recipients (scientists), data producers (clinic staff), and data trustees (platform operators). Each interacts with the data trust system and requires a specific, user-friendly interface to fulfill its role. Single-page web applications, hosted on scalable application servers by the trustee, deliver tailored user interfaces for each role. This setup ensures accessibility and operability across various end devices. Notably, components of the trustee platform operate not only on the trustee's infrastructure but also within clinical infrastructures. This complies with German clinics' strict data security obligations and their reservation regarding data transfer to third parties. In this architecture, adapter services run distributively in participating clinics, linking patients' trust account IDs to their medical records on the clinic side and facilitating anonymized data access per request. Control over the provision of and access to anonymized data remains with the clinic. For research analysis, the trustee's application server aggregates anonymized data and executes analysis scripts within a controlled container environment in the trustee's data center. The results are then reported back to the researcher. Our prototype leveraged Curious Containers [12] for controlled execution, tailored explicitly for scripted experiments. Upon analysis completion, aggregated data is promptly deleted from the trustee's servers, although metadata required for search queries may be cached for efficiency. Access to anonymized patient data by researchers is logged alongside executed scripts and results in a tamper-proof database. This logging simplifies subsequent checks in the event of suspicion and reduces the risk of misuse. While controlled execution environments do not entirely negate abusive behavior, logging significantly raises the bar.

In conclusion, our architecture provides clinics with comprehensive data control, seamless integration into clinical workflows, and secure analysis without exposing clinical record data to researchers. However, it may entail reduced flexibility for researchers in direct data handling and increased computing resource demands for analysis scripts executed on the trustee platform.

B. Empowering patients with dynamic consent

Designing an informed consent process for patient-centered data sharing in sleep research posed several key challenges:

- **Comprehensive understanding:** Ensuring patients understand the risks and benefits of data sharing without struggling with lengthy, complex documents.

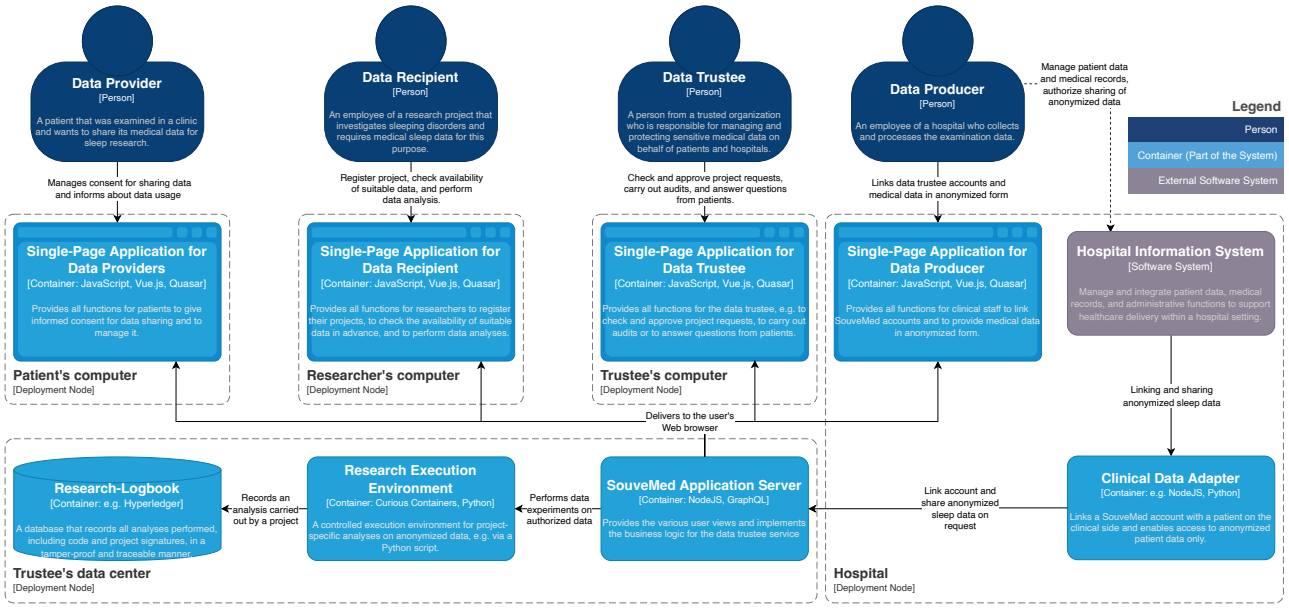


Fig. 1: A C4 model container diagram describing the data trustee's distributed architecture with its essential building blocks. The light blue blocks are part of the system. The dashed boxes describe the different deployment nodes.

- **Flexibility and control:** Providing patients greater autonomy in managing their data compared to traditional broad-consent methods.
- **Data granularity:** Balancing the level of detail for controlling data access to avoid overwhelming patients while still providing meaningful control.
- **Duration and withdrawal:** Facilitating easy withdrawal of consent and managing the duration in line with administrative burdens for data usage.

In current clinical practices in Germany, broad consent is the preferred method, often obtained through lengthy written, legally sound forms [13]. Patients commit to long-term use of pseudonymized data for clinical research, requiring a careful read of extensive information sheets. While revocation is feasible, modifying consent details post-signing is often impractical. In contrast, when developing a data trust platform for sleep medicine, we opted for a dynamic consent approach [11] that improves the process of consent for patients in three ways:

- **Personal consultation:** Patients are informed about the shared use of data in a personal conversation during the clinic visit, which makes it easier to understand the digital information sheet later.
- **User-friendly app:** A dedicated app empowers patients to self-inform, manage consent dynamically, and engage with the process conveniently.
- **Coarse granular data management:** Patients can manage their data records at the level of clinical stays, facilitating ease of control and understanding.

During the clinic visit, patients are briefed on data-sharing risks, opportunities, and procedures, with ample room for discussion. Subsequently, patients can establish a personal data trust account via the trustee platform using their devices. Consultation with their physician allows linkage of their trust account ID to clinical data. Following pseudonymization, patients gain access to and control over their stay data via the app. The consent process involves two steps: (1) confirmation of a digital information sheet and (2) explicit selection of pseudonymized data records for sharing, as illustrated in Figure 2. Patients must confirm their understanding of risks and opportunities before choosing data records and specifying project access preferences. For instance, patients have the option to specify whether access to the data records should be limited to non-profit endeavors or extended to commercial projects. Additional preferences, such as notification preferences for incidental findings, are also indicated.

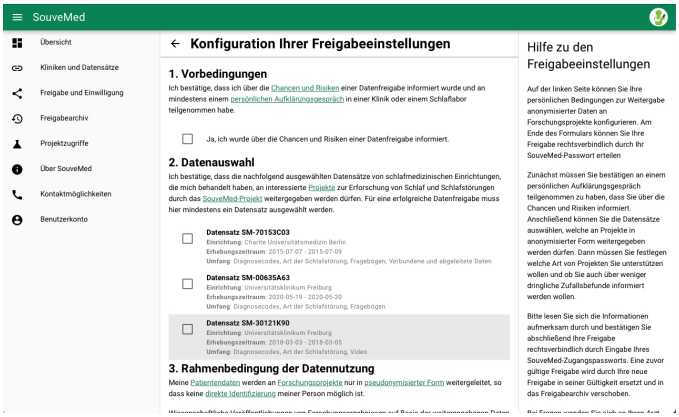


Fig. 2: Tailoring data sharing preferences through an intuitive user interface in the trustee application.

Upon confirmation with their account credentials, data is made available for project requests according to the specified settings. Patients can monitor shared data, associated projects, and responsible parties at any time, with the flexibility to adjust

or withdraw consent as needed.

Our process ensures transparency and patient empowerment, a departure from conventional broad-consent practices. Initial consultations and digital consent forms featuring video aids and supplementary texts democratize access to modern trust systems in sleep medicine. Combining personalized clinic consultations and intuitive digital consent mechanisms fosters patient-centered data management, promoting transparency and autonomy in sleep research endeavors.

C. Secure data requests and analysis for sleep researchers

There are currently two major systems in Germany that facilitate the request and utilization of research data from the healthcare sector for third parties, which themselves go beyond the stage of being research projects. The Health Data Lab (HDL) at the Federal Institute for Drugs and Medical Devices [2] exclusively permits the on-site and off-site use of billing data and statistics from the statutory health insurance funds but does not extend to routine healthcare or research data. Another noteworthy system is the German Portal for Medical Research Data developed by the Medical Informatics Initiative (MII) [3]. However, this platform presently grants access only to public researchers. Moreover, despite the existence of a central platform [14] for data requests, individual legal contracts must be established subsequently with each data-providing institution, complicating the process [15].

In addition, the amount of available data varies depending on the analysis type. For example, while the MII enables centralized and distributed analysis of pseudonymized data, the adoption of broad consent in German healthcare remains limited, restricting the data accessible for centralized analysis. Moreover, distributed analysis is currently limited to R statistics scripts and does not include machine learning approaches. As the platform is still under development, with only university hospitals connected for the most part and many sub-steps still undergoing manual verification, the number of processed data uses has been limited since its activation in May 2023. In addition to these platforms, which are doing pioneering work with regard to the use of research data in Germany, access to medical data and its utilization is currently often perceived as laborious according to a survey of Erler et al. [15].

Considering these findings, the main obstacles in designing a secure data request and analysis process include:

- **Data governance:** Establishing a central point of contact for legally compliant data requests and utilization despite decentralized data storage across various sleep medicine facilities proves challenging.
- **Data privacy and security:** Balancing the protection of sensitive health data and personal information, ensuring access only for authorized users, and taking into account the specific conditions for secondary data use by data providers and producers involves a tradeoff between protecting the privacy and autonomy of patients and in-depth data analysis.
- **Data quality and interoperability:** Standardisation issues in data and infrastructures, alongside varying data quality and formats, hinder proper analysis.
- **Scalability and performance:** Ensuring scalability and performance while maintaining data security and privacy is a balancing act.
- **Transparency and reproducibility:** It takes much effort to ensure that all relevant data, methods, tools, and parameters are accurately documented and transparent for authorized users.

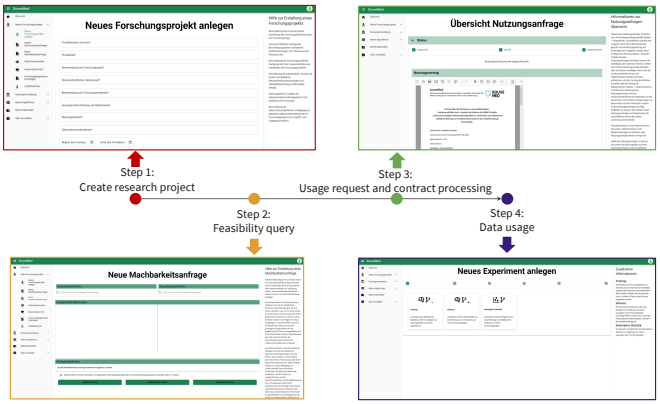


Fig. 3: The streamlined request process involves project registration, pre-checking data availability, requesting access, signing contracts, and finally, utilizing the data.

In order to increase the acceptance of the request processes by the data-providing institutions, the currently established MII processes for requesting data are used as the basis for our work. With this in mind, the four steps outlined in Figure 3 are supported in our process: (1) research project creation, (2) feasibility query, (3) usage request and contract processing, and (4) data usage.

As a first step, researchers must outline a research project with its objectives and purpose of data use. Subsequently, a feasibility query assesses whether the decentralized data trustee has sufficient data to address the project's research questions, incorporating various inclusion and exclusion criteria. Our feasibility query form is based on the design of the MII [16]. The design was extended to constrain the specific type of sleep medicine data required, e.g., for specific questionnaires or polysomnography recordings.

The use of standardized data descriptions based on the *Fast Healthcare Interoperability Resources* (FHIR) standard [17] in combination with FHIR Search [18] facilitates our feasibility queries. Notably, our work introduces standardized descriptions of sleep data (e.g., questionnaires, diagnoses, metadata on sleep medicine recordings such as polysomnographies) using FHIR resources, an aspect not currently addressed by the MII.

Furthermore, we introduced a matched-pairs functionality wherein each test subject is paired with a control subject matching certain influencing factors (e.g., age of ±3 years). Once sufficient data is available, researchers can submit a data usage application akin to the MII's data usage application form [16]. Pre-existing entries from saved research projects and feasibility queries can be directly incorporated into a request to streamline the process. After a legal review by the

trustee and a successful contract conclusion, the de-identified data becomes accessible for research experiments. Researchers can upload and utilize machine learning or statistics scripts as well as existing machine learning models for their experiments. Post-experiment, results can be downloaded, and incidental findings can be reported back to treating physicians to ensure patients' well-being. In addition, unique dataset IDs can be publicly shared with other researchers to improve the reproducibility and transparency of results.

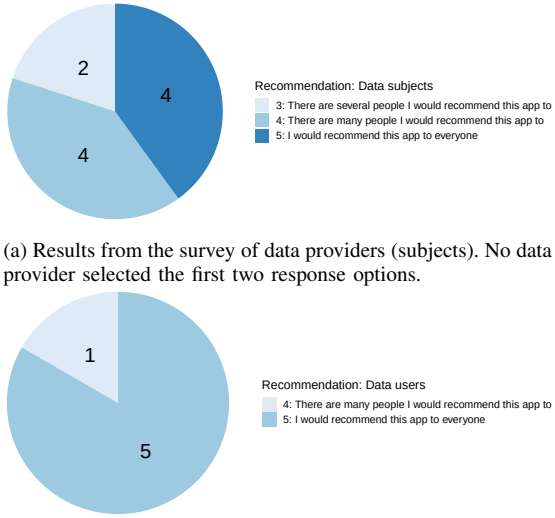
Overall, we used the following approaches in our proposed process to make data requests and analysis more secure, simple, and transparent:

- Establishing the data trustee as a central contractual partner for legally compliant data requests and usage of pseudonymized sleep data from diverse facilities.
- Standardizing sleep data descriptions using FHIR resources.
- Implementing software adapters as uniform interfaces to existing heterogeneous systems in sleep clinics.
- Facilitating collaboration and data sharing between researchers and data producers while protecting data privacy and security and considering their individual conditions for secondary use.
- Designing a user-friendly platform with clear governance policies and streamlined procedures.
- Ensuring the reproducibility of research experiments through unique data set IDs and container-based execution environments.
- Providing a priori availability checks for relevant data without initial contracts, balancing data providers' privacy needs and data producers' business interests.
- Supporting common data usage types, including descriptive statistics and machine learning.
- Enabling data access for both public and private research institutions.
- Enabling reporting of incidental findings without overwhelming data producers or revealing their identities.
- Tamper-proof logging to simplify subsequent checks in the event of suspicion and reduce the risk of misuse.

IV. Evaluation of Data Sharing and Trustee Model

A. Aims and methods

Our evaluation study aimed to assess the proposed data-sharing process and trustee model from the perspective of data subjects, data users, and representatives from data-generating institutions. To this end, we conducted an anonymous survey using online questionnaires. Key elements of the survey comprised the usability of the system, as measured by the user version of the Mobile Application Rating Scale (uMARS) [19], [20] and data subjects' trust, as measured by the Human-Computer Trust Scale (HCTS) [21]. The HCTS consists of 12 items that must be answered on a 5-point Likert scale from 1 ("strongly disagree") to 5 ("strongly agree"). For the uMARS, three out of four sections were presented to the participants: functionality, aesthetics, and subjective quality. One section was excluded from the survey to avoid overlap with other parts of the questionnaire. Responses were provided on a 5-point Likert scale, with higher values indicating greater subjective usability.



(a) Results from the survey of data providers (subjects). No data provider selected the first two response options.

(b) Results from the survey of data recipients (users). No data recipient selected the first three response options.

Fig. 4: Results for the recommendation item of the end user version of the mobile application rating scale (5-point Likert scale).

B. Results

The final prototype was evaluated by 10 data providers (patients) and 6 data recipients (research experts). Data providers demonstrated a high level of trust in the proposed concept, with a mean HCTS score of 4.28 (± 0.80). Functionality was rated highly by both data providers, with a mean rating of 4.50 (± 0.81), and data recipients, with a mean rating of 4.58 (± 0.52). Similarly, aesthetics received favorable ratings, with data providers averaging 4.23 (± 0.96) and data recipients averaging 4.17 (± 0.71). In terms of subjective quality, a majority of both data providers and recipients expressed their likelihood of recommending the system to potential beneficiaries (see Figure 4).

V. Discussion and Conclusion

Addressing the manifold challenges of establishing a data trustee system in the context of sleep medicine requires a comprehensive approach that considers the needs of all stakeholders involved, ensuring both secure and ethical data sharing and use. Our research demonstrated that introducing a user-friendly data trustee app combined with personalized consultations enhances patients' comprehension and engagement in data sharing. A central and trustworthy intermediary seems to give patients the perception that they are cared for and that their data interests are prioritized in line with the GDPR, as demonstrated in our evaluation study by the high level of trust regarding the proposed system. This finding is consistent with studies emphasizing the key role of appropriate communication and involvement of data providers in building trust [22] [23]. Also, our coarse granular data management

approach empowers patients to maintain significant control over their data, giving them greater autonomy and sovereignty in the data-sharing process compared to approaches based on broad consent. In addition, the feeling of being asked and taken seriously as a data provider is strengthened. Furthermore, we have developed a digital consent and administration process for data providers as a possible alternative to the current paper-based processes used in German initiatives. From the perspective of data recipients, we have mapped out a digital process incorporating data availability queries, data requests, contract processing, as well as scientific and incidental reporting. Both from the perspective of data providers and data recipients, our evaluation found that the developed system offers good usability, which is crucial for the acceptance of the system. In addition, both data providers and data recipients benefit equally from the legally secure framework offered by a data trustee, which in turn reduces the barrier caused by legal uncertainties. Our proposed platform consolidates all these features into a single system, providing researchers with a centralized digital hub unlike any existing systems.

In addition, we are the first in Germany to describe domain-specific data related to sleep laboratory stays for secondary use through FHIR resources, aligning the concept of a data trustee with FAIR data principles (Findable, Accessible, Interoperable, Reusable). By employing standardized data descriptions combined with robust security measures, we ensure both privacy and interoperability, facilitating collaboration between researchers and sleep clinics. Moreover, the implementation of tamper-proof logging enhances the traceability and detection of data misuse, thereby reinforcing ethical data practices in sleep medicine research.

However, it is essential to acknowledge the limitations of our work. The sample size of 16 participants across all user groups may only represent a part of the user population, potentially limiting the generalizability of the study findings. Nevertheless, by acquiring initial impressions in the specific sleep medicine use case, we have gained valuable insights and outlined preliminary solutions for addressing design challenges in data trust systems, laying the groundwork for further research. Through the adoption of a decentralized, distributed trust system architecture, we have showcased the potential of a socio-technical data trustee system as a neutral intermediary that fosters trust and collaboration among stakeholders in the field of sleep medicine, enabling a fair balance of interests and facilitating a trustful exchange and secondary use of data.

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