Statement

March 2025

Key Perspectives on the TEHDAS2 Guidelines for Implementing the European Health Data Space

The TEHDAS2 joint action prepares the ground for the harmonised implementation of the secondary use of health data in the European Health Data Space (EHDS). Bitkom welcomes the opportunity to comment on the draft guidelines within the TEHDAS2 project. A focus on a unified implementation of the secondary use of health data across the EU is essential for the successful realization of the EHDS. The guidelines represent a crucial milestone in this process.

Bitkom represents over 2,200 companies from the digital economy, with a strong focus on driving digital transformation, including in the healthcare sector. Its members include IT manufacturers, pharmaceutical companies, startups, and other players contributing to digital solutions and innovations. Our member companies have carefully reviewed the **Wave 1 guidelines* (5.1, 5.3, 6.2, 7.1)** of the TEHDAS2 joint action and offering feedback through the public survey both individually and through Bitkom. We greatly appreciate the public feedback process; however, we would like to summarize our key concerns in the following:

1. **Metadata and Health Data Standards:** The metadata description should better incorporate established health data standards like FHIR, SNOMED, and LOINC, as they are crucial for interoperability but are not adequately addressed. Additionally, datasets and reference information are already collected in other

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M5.3 Draft technical specification on the national metadata catalogue
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areas, such as data catalogues from EMA, OHDSI, and clinical trial registries. We would encourage all these initiatives to work towards a common minimal description of these datasets to promote interoperability, especially in a cross-border context.

2. **Role of Private Data Holders**: The role of private data holders should be reflected on more comprehensively. It needs to be examined to what extent the EHDS influences the competitive conditions for private companies and how private data hubs can contribute commercially. The compensation structure for data holders should be clearly defined and made transparent to encourage their active participation. The accreditation process as a Trusted Health Data Holder and the relationship of the EHDS with the Darwin-EU initiative should be thoroughly explained. It remains to be clarified whether private data holders have the opportunity to reject requests.
3. **Access Rights and Anonymity:** The documents should include a property to clearly identify if the data contains intellectual property, trade secrets, or commercially sensitive information, along with appropriate access controls, and clarify who has access to the metadata descriptions and at what level of detail to address concerns about data holders' intellectual property.
4. **Regulatory Challenges regarding GDPR**: To ensure that GDPR is maintained for pseudonymized data throughout its entire dissemination, clear regulations and technical clarifications regarding pseudonymization and matching of data sources (e.g., "research pseudonym") should be developed. Additionally, a precise definition of anonymous data is required. Additional guidance for the interaction of GDPR and EHDS is appreciated to avoid confusion, especially in terms of the data protection prerequisites necessary for the data permit.
5. **Decentralized vs. Centralized Data Provision:** The question of whether Secure Data Environments (SDE) should be provided by the Health Data Access Body (HDAB) in a decentralized or centralized manner, as well as the possibility for data holders to offer such SDE, needs to be clarified.

Overall, it is important to clearly define the role and involvement of private data holders in the EHDS. This would help ensure that their valuable data can be integrated into the system without jeopardizing their commercial interests. We welcome a structured and transparent discussion on these topics to promote a sustainable and fair data economy in the healthcare sector.

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Bitkom vertritt mehr als 2.200 Mitgliedsunternehmen aus der digitalen Wirtschaft. Sie generieren in Deutschland gut 200 Milliarden Euro Umsatz mit digitalen Technologien und Lösungen und beschäftigen mehr als 2 Millionen Menschen. Zu den Mitgliedern zählen mehr als 1.000 Mittelständler, über 500 Startups und nahezu alle Global Player. Sie bieten Software, IT-Services, Telekommunikations- oder Internetdienste an, stellen Geräte und Bauteile her, sind im Bereich der digitalen Medien tätig, kreieren Content, bieten Plattformen an oder sind in anderer Weise Teil der digitalen Wirtschaft. 82 Prozent der im Bitkom engagierten Unternehmen haben ihren Hauptsitz in Deutschland, weitere 8 Prozent kommen aus dem restlichen Europa und 7 Prozent aus den USA. 3 Prozent stammen aus anderen Regionen der Welt. Bitkom fördert und treibt die digitale Transformation der deutschen Wirtschaft und setzt sich für eine breite gesellschaftliche Teilhabe an den digitalen Entwicklungen ein. Ziel ist es, Deutschland zu einem leistungsfähigen und souveränen Digitalstandort zu machen.

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