EORTC's position on the European Health Data Space (EHDS) and its proposed Guidelines

The European Organisation for Research and Treatment of Cancer (EORTC) welcomes the TEHDAS2[1] initiative developing guidelines and technical specifications for the seamless creation of the European Health Data Space (EHDS), as there is an unmet need to facilitate health data sharing across borders.

The EORTC would like to share its views and recommendations as a sponsor of clinical trials and holder of clinical data, regarding the primary and secondary use of such health data.

1) Primary use: data quality, integrity, and readiness are key

Under the EHDS, data from completed clinical trials should be made available for sharing by data holders. Premature disclosure of unvalidated datasets could undermine the scientific integrity of the clinical trial as well as risk misinterpretation and inappropriate conclusions that could potentially mislead public-health decision-making. Only mature and validated data should be shared.

It is important to support scientists taking responsibility for the conduct of clinical trials generating valuable data. They should be given sufficient time to fully analyse and publish the results. Researchers having conducted the clinical trial should be incentivised to continue to do so and therefore keeping clinical research in Europe.

Suggestions: 1) It should be clarified that clinical trial completion is defined as when the clinical trial is mature for all analyses defined in the clinical trial protocol and the database has been cleaned and frozen for these analyses. 2) It should be confirmed that researcher will have enough time to complete their primary use of the data. Therefore, a 12-month exclusive data access period should be allocated for data holders after the completion of a clinical trial. This will ensure EHDS alignment with the Clinical Trials Regulation 536/2014 obligation for the clinical trial sponsor to publish the results in the Clinical Trials Information System (CTIS) within 12 months from study completion.

2) Secondary use:

a) Operational feasibility:

Managing data requests requires significant resources, and an unpredictable volume of requests could disproportionately burden data holders managing large databases. In addition, data access bodies could delegate extra tasks to the data holders beyond data extraction.

Suggestion: Member states should define limits on the volume of requests and allow refusal rights for data holders in unstainable situations.

b) Scientific scrutiny:

Data access body appointed by member state will decide on data access requests.

Suggestions: As experts in the field, data holders should have the possibility to assess the value and the scientific relevance of the request and to share their views with the data access body.

[1] TEHDAS2 is joint action funded by EU involving 29 countries and preparing guidelines and technical specifications for implementing the EHDS. https://tehdas.eu/project/

Especially when the request is not be acceptable on scientific ground e.g. when the requestor is planning to duplicate the analysis conducted by the data holder as documented in the CTIS or when methodological weaknesses are identified.

c) Intellectual Property Rights:

The handling of Intellectual Property Rights (IPR) in EHDS brings significant uncertainties. Data holders should not be placed at a competitive disadvantage.

Suggestions: The EHDS must explicitly clarify the scope, enforceability, and practical application of IPR when data are accessed, processed, or reused. The database *sui generis* right established under Directive 96/9/EC on the legal protection of databases provides a comprehensive intellectual property regime designed to recognise and secure substantial investments made by data holders. It is essential that the EHDS framework upholds this protection. It is crucial to maintain a fair and proportionate balance.

d) Populating the EHDS data catalogue:

Some clinical research organisations hold data from hundreds of clinical trials. Populating the EHDS catalogue will therefore require substantial effort. All existing electronic data are in the scope of the EHDS independently of the data's collection or registration date.

Suggestions: Member states should 1) limit the retroactivity of the reporting obligation e.g. clinical trials completed more than 10 years ago should not be referenced in the EHDS catalogue 2) provide data holders with clarity on how much time they will have to fulfil their obligations once the EHDS catalogue will become operational.

e) Data harmonisation

It is not yet specified in the guidelines if data structure/standards should be harmonised as it is recommended in the EHDS whereas 87. We urge member states to consider such obligation very carefully since it may create massive workload for data holders.

Suggestion: Data holders should be allowed to use one of the established data standards such CDISC in oncology.

About EORTC

The European Organisation for Research and Treatment of Cancer (EORTC) is a large independent cancer clinical research organisation. The EORTC has delivered investigator driven, practice changing clinical trials since 1962. Its mission is to improve survival and quality of life of cancer patients. The EORTC is a not-for-profit independent organisation performing multidisciplinary clinical research activities across tumour types. EORTC's activities involve on a voluntary basis more than 2800 doctors and scientists from some 900 university hospitals in 48 countries. EORTC clinical trials are involving several thousands of patients on a yearly basis. The scientific activities of EORTC are strictly peer-reviewed and subject to quality assurance/ quality control programs. The EORTC operates on an independent basis, and in this capacity can work in partnership with the pharmaceutical industry. EORTC has contributed to several success stories in terms of the development of new anti-cancer drugs including registrations by the FDA and the EMA. More information at www.eortc.org