MEDICT

The MEtadata platform for DIgital Clinical Trials

IEEE EMB Standards Committee Sharing

30 August 2021

Karger

MEDICT 2021

What is MEDICT?

MEDICT is a pre-competitive platform to share metadata of digital clinical trials from industry or academia. Karger manages the platform and guarantees the neutrality, transparency and curation of the metadata.

We will build the platform following the FAIR principles:

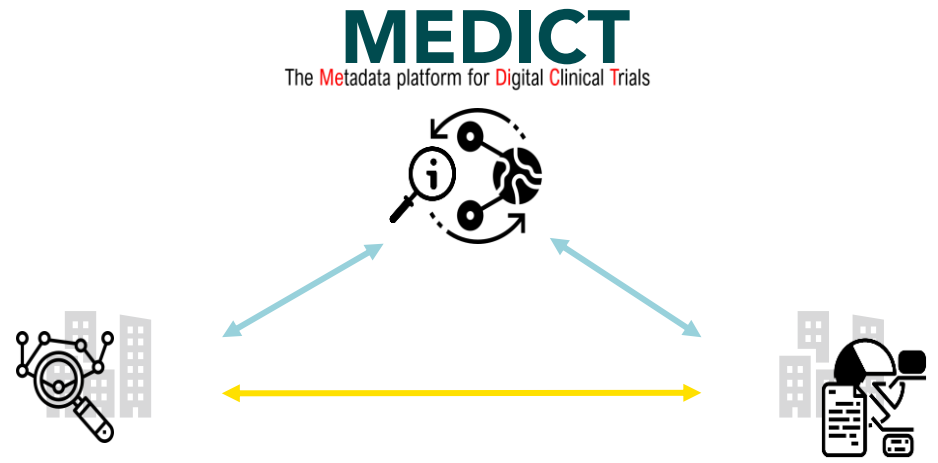
F indable – metadata is easily found by users

A ccessible – facilitate the sharing of metadata*

I nteroperable – develop metadata standards based on common ontology

R eusable – the metadata is reusable when following the same standards and annotations

* clinical data remain the property of their owner



contributor of data sets

MEDICT will curate, validate and make accessible contributor's metadata through a structured and standardised submission process.

procurer of data sets

MEDICT will offer the opportunity to easily search for a study and connect with the researchers of said study.

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Project Background

the "Why"...

Digital clinical trials generate vast amounts of complex datasets in the area of medical measurements, diagnosis and treatments. There is a need to standardise and structure these newly generated datasets for ease of sharing and reanalysis. Sharing of these datasets will favour scientific exchange in the area of digital health and personalised healthcare.

the "How"...

Through engagement and collaboration with multi-stakeholder groups - pharmaceutical industry, biotechnology companies, regulatory bodies, academia, vendors, societies and foundations - Karger hopes to offer a robust and user friendly Open Access metadata platform with a jointly developed standard based on common ontologies.

the "What"...

MEDICT will host the metadata of digital clinical trials which will allow users a grounding from which to acquire/share datasets with relevant parties. The platform will not host raw data of the contributor but rather support the collaborative ecosystem of data sharing in the scientific community for precompetitive development. Reusability of datasets will also prove to be cost effective for future digital clinical trial studies.

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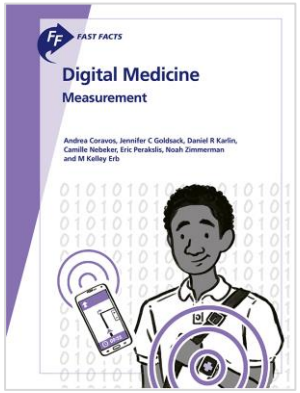
About Karger

History

As a publisher, Karger has long standing experience in reviewing and curating scientific knowledge. A metadata sharing platform complements Karger's traditional publishing activities, expanding the range of its products and services to the scientific community.



Expertise

Karger serves as a hub for the Digital Health community as the publisher of the Digital Biomarkers journal and related publications. The journal bridges various disciplines and supports the community to develop novel ways to advance the emerging field.

Independent

Karger is well connected internationally and is a neutral partner for academia and industries alike. This allows the platform to be managed in an unbiased and transparent manner.

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Vision

Completing the Cycle of Knowledge

The MEDICT project is in line with the long term strategic vision of Karger. In the last year MEDICT has taken shape as we gained more insights through discussions with industry on how the platform can better meet their needs. At this point of the journey, we have an *early stage* prototype of the platform that we will improve through collaborations with relevant stakeholders.

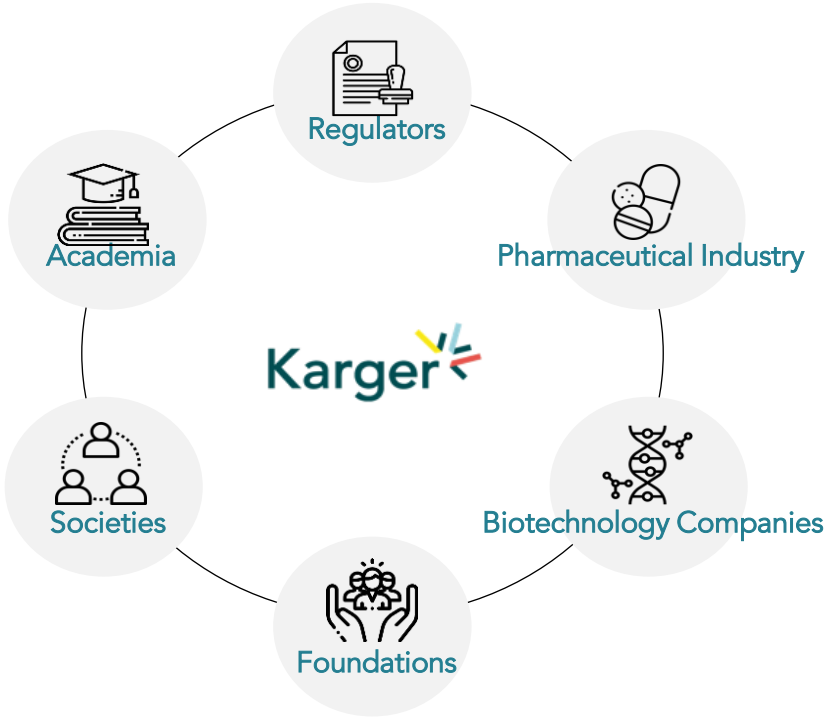
Objective

- Establish a clear metadata structure
- Create collaborations with each stakeholder group
- Launch a minimum viable product (MVP) in 2022

Business Model

Metadata from MEDICT will be published Open Access under a suitable CC license.

Revenue is intended to be generated through a "DPC" (Data Processing Charge) model, comparable to an "APC" (Article Processing Charge) for Open Access journals, and other forms of partnerships, integrations and sponsorships.



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Roadmap

Study List

ID	Title	Investigator	Institute	Research Type	Therapeutic Area	Sensors	Endpoints	Algorithms	Link
1	Validity of accelerometry in step detection and gait speed measurement in orthogeriatric patients	Alexander M. Keppler	Novartis	Clinical	Ostheoporosis	Camera, Accelerometer	Real-world walk scenario	Fast Fourier Transform (FFT), Hilbert transform, support-vector machine (SVM)	view
2	Example Study Title 1	Investigator 1	Institute 1	Academic	Cardiovascular	Accelerometer	Total Sleep Time	Statistics, Machine learning	view
3	Example Study Title 2	Investigator 2	Institute 2	Clinical	Mental Health	Gyroscope	Wake Time After Sleep Onset (WASO)	Machine Learning support-vector machine (SVM)	view

Feb 2021

Discovery

Exploratory phase with potential stakeholders

Focus Areas:
- Business Case
- Project Charter
- Proof of Concept

Jun 2021

Prototype 1.0

Core Functionalities

Software: LabKey

Focus Areas:
- Metadata structure
- Study registration form
- Listing of submissions

Fall 2021

Converging Expertise

Collaborative Success

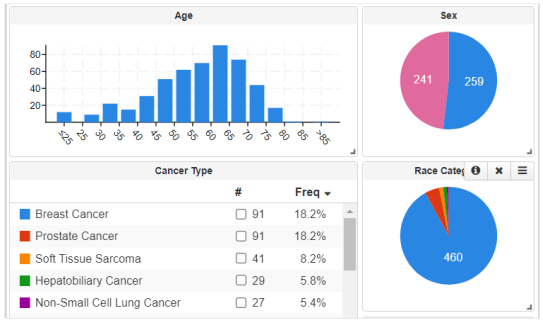
Introduction of the prototype to stakeholders to elicit feedback and areas of improvement

Focus Areas:
- Assembling MEDICT WG
- MEDICT WG 1st Workshop
- Formal discussions with regulators

Prototype 2.0

Form Follows Function

Focus Areas:
- Metadata restructuring
- Search function
- Dashboard display
- Back end integration



Early 2022

MEDICT MVP

Closer to Market

Launch of the MVP to prospective users

Focus Areas:
- Data exchange model
- Business model

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