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Developing a data sharing policy for InTBIR

Why share data?

Isabelle Gagnon (PedCDE)

Joanne Fleming (CREACTIVE)



Why share data?

- InTBIR community has an ethical duty to widely share data collected on participants consenting to take part in interventional and non-interventional clinical studies
- Taxpayer has invested a lot of money to fund the InTBIR studies, making it a duty to promote maximum exploitation of collected data.
- Some jurisdictions made it mandatory to use CDEs to permit data sharing with other members of InTBIR consortium



Why share data?

- It will become mandatory for all manuscripts submitted to ICMJE journals to contain a data sharing statement as of July 2018.
- It is planned to publish some joint InTBIR papers so prompt action is required...



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Data sharing policy

InTBIR has a duty to create a data sharing environment which :

- is secure for the participants,
- protects ownership,
- clearly assigns authorship credit.

... prompting the need for a series of interlinking data sharing policies...



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- Data sharing policy
- Informed consent policy
- Publication policy
- Implementation of data sharing platforms



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Informed consent policy

- To permit data sharing, participants need to have signed an informed consent to this effect.
- In data sharing framework, InTBIR must implement an informed consent policy for all members.



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Informed consent policy

The informed consent protocol must include:

- minimum wording to permit data sharing, including permission for cross-border data transfer
- minimum data encryption and protection standards to ensure that data are exchanged in a secure network



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Publication policy

The InTBIR publication policy must envisage:

- inclusion of a data sharing statement in all InTBIR publications
- authorship credits
- data access policy



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Implementation of data sharing platforms

Level I

Development of federated databases at the level of the three macro areas of InTBIR:

- Canada (Ontario Brain Institute) (?)
- USA (FITBIR)
- Europe (Human Brain Project)



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Implementation of data sharing platforms

Level I

Europe (Human Brain Project)

CREACTIVE's data has been integrated in HBP's medical informatics platform. Data summaries are visible in the platform with other research data.

Federation has been stimulated by splitting the data provided along the different CREATICE centers.

In analysis terms, stats methods can be run within centers or across centers.



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Implementation of data sharing platforms

Level II

Development of a federated database permitting data sharing among the macro-level databases of Canada (Ontario Brain Institute [?]), USA (FITBIR) and Europe (HBP)



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Implementation of data sharing platforms

Drawing up of a protocol determining:

- which data to share within InTBIR
- timing of data access (implementation of embargoes)
- multilevel data access:
 - at individual study level
 - at macro area level
 - at InTBIR level
 - by general scientific community



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Conclusions

There is now some urgency to develop a data sharing policy at various levels.

- To meet the original InTBIR mandate
- Ethical duty to patients and taxpayers
- Data sharing is becoming mandatory



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Conclusions

Fostering data sharing through federated databases
needs InTBIR leadership !!



Policies Work Group Members:

Coordinators:

- *Mark Goldammer (EU) – (A special thanks to Mark for all his hard work coordinating the group)*
- *Stephane Hogan (EU)*

Co-chairs:

- *Isabelle Gagnon (PedCDE)*
- *Joanne Fleming (CREACTIVE)*

Members:

- *Giuseppe Citerio (CENTER-TBI)*
- *Ramon Diaz-Arrastia (Track TBI)*
- *Carolyn Emery (Safe to play)*
- *Ferath Kherif (HBP)*
- *Nick Reed (Neurocare)*
- *Laurie Silfies (ADAPT)*

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