



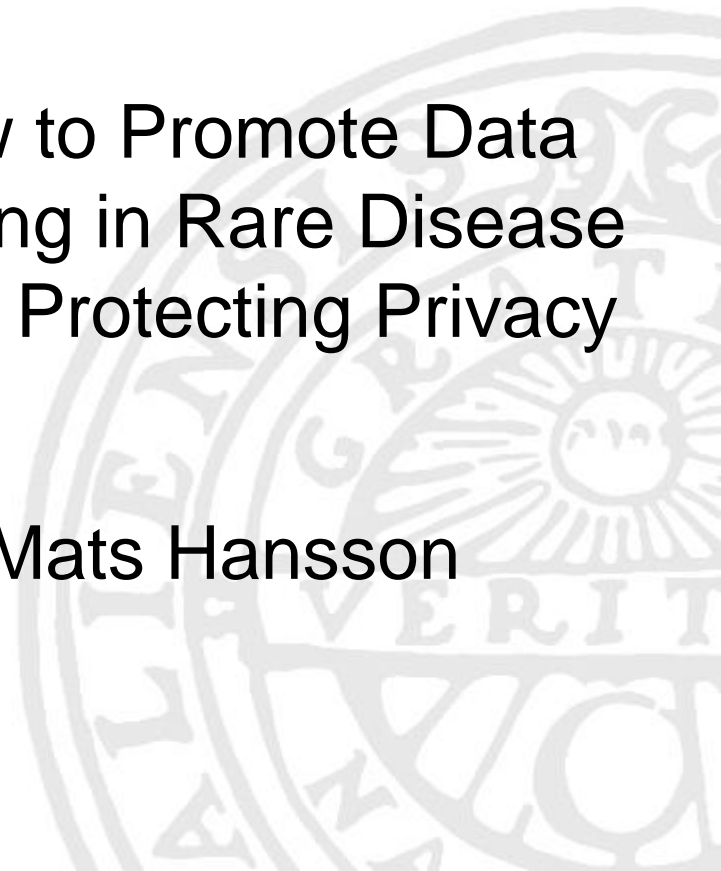
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How to Promote Data
Sharing in Rare Disease
while Protecting Privacy

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Sharing of data & biospecimens



- Essential for the discovery, new knowledge creation and translation of various biomedical research findings into improved diagnostics, biomarkers, treatment development, patient care, health service planning and general population health



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Sharing of data & biospecimens



- Of highest importance for Rare Disease (RD) research because of the scarcity of research participants, samples, data, resources and researchers for any given RD.



While protecting privacy



- However, personal data cannot be accessed openly without restrictions due to privacy regulations and concerns. There are also legitimate intellectual rights of researchers and institutions collecting the data that should be acknowledged.



Not “open access”



- But a regulated access for protecting privacy of participants and respecting scientific values and ethical norms



RD-CONNECT Code of Practice - Principles



- **I. Respect for privacy and autonomy:** stewardship implies protection of participants' privacy. Privacy protection measures should be in place and informed consent must provide provisions for future as yet unspecified research using data and bio-specimens.



RD-CONNECT Code of Practice - Principles



- **II. Reciprocity:** stewardship also implies giving back. Feedback of general results should be channelled to institutions and patients.



RD-CONNECT Code of Practice - Principles



- **III. Freedom of scientific enquiry:** stewardship should encourage openness of scientific enquiry, and maximize data and bio-specimen use and sharing so as to exploit their full potential to promote health.



RD-CONNECT Code of Practice - Principles



- **IV. Attribution:** the intellectual investment of investigators involved in the creation of data registries and bio-repositories is often substantial, and should be acknowledged by mutual agreement.



RD-CONNECT Code of Practice - Principles



- **V. Respect for intellectual property:** the sharing of data and bio- specimens needs to protect proprietary information and address the requirements of institutions and third-party funders.



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RD-CONNECT Code of Practice



- Conditions specified in 21 rules of conduct
- Adherence agreement
- User verification



Privacy and identifying individuals



- A growing concern that de-identification or coding of personal data and biospecimens is not sufficient for protecting research subjects from privacy invasions and possible breaches of confidentiality due to the possibility of unauthorized re-identification.



Privacy and identifying individuals



- At the same time, there is a need in medical science to be able to identify individual patients. In particular for rare disease research so that data and biosamples from multiple independent studies can be shared across borders.



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Privacy and identifying individuals



- Open and transparent information
- Adequately informed consent
- The use of safe unique personal identifiers, e.g, the GUID or HD identifiers



Adherence agreement:



- In addition to the rules laid out by the Code, the following project specific rules shall apply:
 - a. There will be no attempt to try to identify or contact data or donor subjects.
 - b. Accessed data and biospecimens will not be redistributed.
 - c. Access codes and user logins are specific to the identified user and are strictly non-transferrable.
 - d. Accessed datasets will be destroyed once they are no longer used.



References



- Mascalzoni D, Dove E, Rubinstein Y, Dawkins H, Kole A, Mc McCormack P, Woods S, Riess O, Schaefer F, Lochmüller H, Knoppers B, Hansson M, International Charter of Principles for Sharing Bio-specimens and Data, *European Journal of Human Genetics*, 2014;23:721-728.
- Hansson MG, Lochmüller H, Riess O, Schaefer F, Orth M, Rubinstein Y, Molster C, Dawkins H, Taruscio D, Posada M, Woods S, The risk of re-identification versus the need to identify individuals in rare disease research, *European Journal of Human Genetics* 2016;24(11):1553-1558.