

Annex VIII

DIRECT “Fort Lauderdale principles” for data access, analysis, publication and dissemination

This annex details the ‘principles’ to which all analysts are expected to adhere within the DIRECT studies.

Principles for Analysts

The DIRECT data and samples will consist of a rich resource of value to the consortium and wider research community. There is a need to protect the intellectual property of the consortium members whilst encouraging a spirit of openness both within the consortium and the wider research community.

All encompassing general principles are considered to be:

- Transparency and honesty amongst DIRECT scientists.
- Accessibility for all DIRECT consortium members with a valid research question.
- Analysis only with prior declaration and approval from the management board (via the DAC).
- Fairness and suitable acknowledgement of all involved.
- Collaboration, integration and inclusion amongst all DIRECT participants.

Data deposition

In accord with Fort Lauderdale principles, data generated by DIRECT will be deposited in a managed access resource, such as the European Genome-Phenome archive. This data will consist the genomic data and associated derived phenotype e.g. GWAS data plus associated drug/treatment response/non-response status. Data deposition will occur, at the latest, on completion of the DIRECT study, and potentially earlier with the publication if this is a requirement of the publication process.

Individual linked data across multiple phenotype and genomic levels will be maintained within the DIRECT database for access by DIRECT consortium members but will not be made openly available. Access to this linked data for non-consortium members will be by collaboration, and approval of the management board.

Return of data to sample providers

All data generated during DIRECT where samples do not arise from prospective DIRECT studies will be returned to the sample providers. This data may not be used to address research questions involving any DIRECT phenotype for the duration of the DIRECT project, but may be used freely by the sample provider for any other purpose.