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• “Do it yourself” Workshop OpenClinica
TOOLS WITHIN TRAIT

WHAT IS OPENCLINICA?

An eCRF application (electronic Case Report Form) to collect data collected for clinical events and observations in clinical studies:

- Web based (suited for multi-center studies)
- Open source
  - Maintained & coordinated by OpenClinica.com
  - More than 10k installations worldwide
- Controlled environment to collect high quality data
- OpenClinica data model based on CDISC / ODM format
FEATURES OF OPENCLINICA

- Study setup: design Case Report Form (CRF)
- Submit data: manual / upload from database
  - dynamic form logic
- Monitoring data:
  - automated validation checks and manual queries (discrepancies)
- Access depends on role user
- Extract (subsets of) data

WHY OPENCLINICA?

- Easy to develop basic studies and CRFs
  - supports scripting for more advanced features
- Easy web interface
- Monitoring module
- Supports key regulatory guidelines
- Supports “21 CFR Part 11” and GCP
- Active user community
THE WORKSHOP SETUP (1)

- OpenClinica environment:
  https://sandbox.openclinica.nl/

- Two user accounts: (replace # by number given to you)
  1) CRC (data entry person for 1 site)
  2) DM (=Data manager. Data entry for complete study; data extract; build a study)

- Follow the demo manual and/or DIY

THE WORKSHOP SETUP (2)

- Data entry of CRF pages
  - navigation in a study (Events, CRF pages, sections on a CRF page)
  - different types of fields
  - creating discrepancies

- Discrepancy management
  - create discrepancies
  - discrepancies overview
  - solve discrepancies

- Audit log

- Export of data

- Create your own study (optional)
OPENCLINICA CONCEPTS

- Event: e.g. visit on which a patient comes in for measurements
- CRF: (Case report Form) data entry screen for all measurements and questions at certain visit
- Discrepancy: created automatically when validation check is not met for an entered value or can be added manually
- Site: participating hospital/institute in a study

LYGATURE DEMO STUDY

- Visit 1
  - Demographic data
  - ECG data
  - Link to Brain scan (XNAT)
- ECGs (repeated)
  - Follow-up ECG data
- Adverse Events

= any undesirable experience associated with the use of a medical product in a patient
QUESTIONS?