Electronic Data Capture in China
—— Current Situation and Challenges

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Outline

01 Definition of eDC in China

02 Current Situations

03 Challenges for eDC

Electronic Data Capture

Similar to western country

- **Electronic tool to collect, manage, and report clinical and laboratory data**
- **Allows investigators to enter data directly in database**

EDC modules in China

- Questionnaire / Case Report Forms (data entry and check)
- Query management
- Randomization (if RCT)
- Data extraction
- Reporting
- Lab data uploads (options, depends on studies)
- Coding (not always, depends on sponsor)

Manners of EDC in China

Two manners

- **Manner 1: Web-based data entry (no local installation)**

  - Usually for clinical trials

  - SFDA regulation: only the investigators who working in SFDA approved high level hospital can participate in clinical trial

  - Situated in big city, very easy to access internet (SFDA approved high level hospital)

Manners of EDC in China

Two manners

- **Manner 2: Remote data entry (local installation)**

  - Usually for epidemiology study/survey/post-market clinical trial

  - Many community-based hospital participate in this study

  - They situate in rural area or in small city very far away from central city

  - Very difficult to access internet, or the speed of internet is very slow

Situation of EDC in China

- Traditionally, free data capture systems were used
  - EpiData, ACCESS, SPSS, Excel
- Now, more and more commercial eDC systems
  - Oracle Clinical (OC)
  - Medidata Rave
  - Phase Forward
  - Data Fax
  - In-house System (-CIMS, Clinical Informatiics Management System)

Situation of EDC in China

- Very rare used in China (>10,000 drug/MD clinical trials, < 5% trials using eDC)
- Most eDC trials are sponsored by international big pharmaceutical / MD company
- Many trials are post-market trial (not for SFDA approval), since
- SFDA regulation: sponsor must submit paper-based CRF for new drug / new MD application

Limitations to the Broader Implementation of eDC

The reasons that government does not require eDC system for clinical data collection

- Cost : very expensive (OC: about 200,000US$ for academic version)
- Security problem (cannot store data locally: Medidata)
- Feasibility: not all hospitals can access internet
- Don't want to promote commercial eDC system (government prefer to develop eDC themselves)
- Sponsor does not want to pay eDC

Limitations to the Broader Implementation of eDC

- PI usually director of some Division, they cannot enter data themselves (asking low level doctor to do it
- Doctors are quite busy (on average, one doctor must see >20 patients per day)
- No time to enter data by themselves, and also, they are not quite familiar with eDC system
- Prefer using paper-based CRF (ask data processing center to enter data)
- Not easy to broader implementation of eDC in clinical practice of China

eDC at the MRBC of National Center for Cardiovascular Diseases

The MRBC of NCCD

------ Medical Research of Biometrics Center

- Academic Research Organisation (ARO)
- Focus on
  - Drug / medical device clinical trial
  - Outcome research
  - Training & Consulting (SFDA, industry)
- Many therapy areas: Cardiovascular, Cerobrovascular, renal, DM, neurological, cancer, psychiatry, etc.
- Very good reputation in SFDA of China

Data Management at the MRBC

Data Management

Team created in 2003

- 16 employees (DMs, programmers, etc.)
- Responsibilities
  - CRF design
  - Database setup
  - Data cleaning & query generating
  - Coding & reporting
- Data collection method
  - Paper-based
  - eDC-based: OC, CIMS, EpiData, in-house software

EDC in MRBC of NCCD

- OC (Oracle Clinical)

- CIMS (Clinical Informatiics Management System)
  - Developed by US company
  - Meet CFR 21 part 11
  - Passed IQ, OQ, PQ validation

- eDC in house (developed by ourselves, passed IQ, OQ, PQ validation)

Projects used eDC in MRBC

Four MD clinical trials used eDC completely

- 2 DES, Stimulator of brain, Cancer
- All eDC developed by ourselves
- Distribute CRAs working in site to help doctors to enter data

CARE CHINA-DIABETES

All function modules（J&J Medical Center, China)

- Data Input
- PD Input
- PD Confirm
- Image Upload
- Data Output
- Sign off form
- Query Management
- Data Review
- Delete Form
- Log Record
- Status Reporting
- Advanced Search
- System Management
- Follow up Warning
- CEC Event

Challenges of eDC in MRBC

Although we are top ARO in China

- Among 70 trials annually, only 4 projects using eDC completely

- Most trials use paper-based CRF

- Very difficult to broader implementation of eDC

So,
how to reduce the gap with developed countries turns out to be a great challenge

Government

Industry

Academy

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Cooperation to broader implementation of eDC in China?

Thank You!

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