



Electronic Data Capture in China

—— Current Situation and Challenges

Prof. Li Wei

National Center for Cardiovascular Diseases

May 20, 2012, Miami



Outline

01 Definition of eDC in China

02 Current Situations

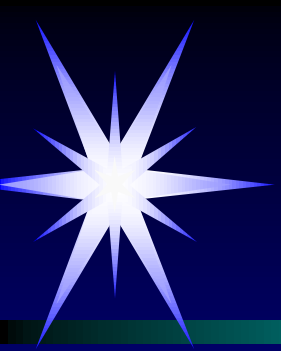
03 Challenges for eDC



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

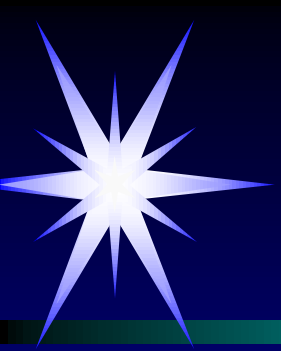
- **Very rare used in China (>10,000 drug/MD clinical trials, < 5% trials using eDC)**
- **Most eDC trials are sponsored by international big pharmaceutical / MD company**
- **Many trials are post-market trial (not for SFDA approval), since**
- **SFDA regulation: sponsor must submit paper-based CRF for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



Limitations to the Broader Implementation of eDC

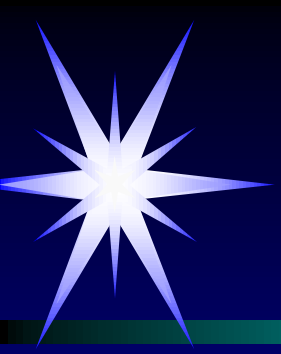
The reasons that government does not require eDC system for clinical data collection

- **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**



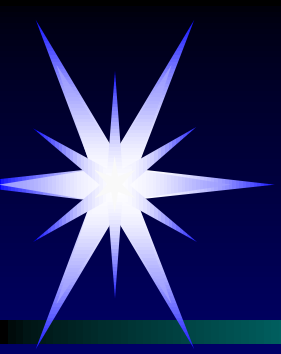
**eDC at the MRBC of
National Center for Cardiovascular
Diseases**



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, Cerebrovascular, 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

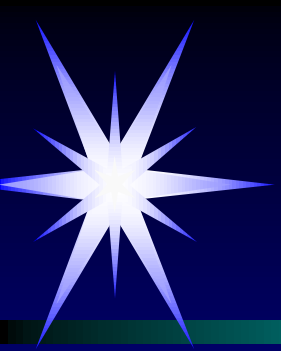
- OC (Oracle Clinical)**
- CIMS (Clinical Informatiics Management System)**
 - Developed by US company**
 - Meet CFR 21 part 11**
 - Passed IQ, OQ, PQ validation**
- eDC in house (developed by ourselves, passed IQ, OQ, PQ validation)**



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)

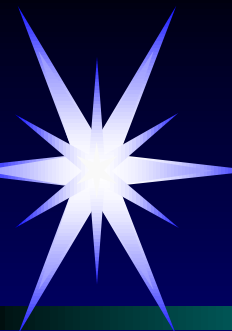
- | | | |
|--|--|--|
| <input type="checkbox"/> Data Input | <input type="checkbox"/> PD Input | <input type="checkbox"/> PD Confirm |
| <input type="checkbox"/> Image Upload | <input type="checkbox"/> Data Output | <input type="checkbox"/> Sign off form |
| <input type="checkbox"/> Query Management | <input type="checkbox"/> Data Review | <input type="checkbox"/> Delete Form |
| <input type="checkbox"/> Log Record | <input type="checkbox"/> Status Reporting | <input type="checkbox"/> Advanced Search |
| <input type="checkbox"/> System Management | <input type="checkbox"/> Follow up Warning | <input type="checkbox"/> 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**





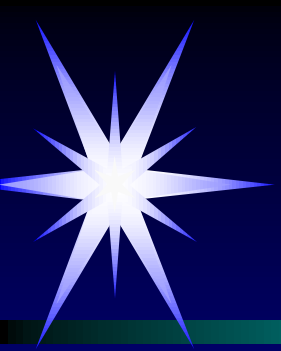
Government

Industry

Academy

.....

**Cooperation to broader implementation
of eDC in China?**



Thank You!



Prof. Li Wei

Email: liwei@mrbc-nccd.com