Topics

• Old Habits Die Hard
• New Habits and Opportunities of a Blank Slate:
  – Using a 21st Century Technology Infrastructure
  – Data Standards for Interoperability
  – Treating Information as a Critical Asset
  – The Convergence of Healthcare and Research
• Conclusions
Old Habits Die Hard

It is not sufficient to apply new technology to old processes
Clinical development transformation...
Merck is shifting drug development toward embracing a “network” of partners

Merck External Basic Research (EBR) team expects to deliver 25% of early pipeline from external partners by 2013 (Source: Pharma Focus Asia)
New Habit: Cloud Computing

- Faster implementation for less cost and bother
- Rapid scalability
- Ability to support multiple devices
- But real pay-off will be when we can cross-use shared data
Old Habit: Paper CRF Process

Source: Paul Bleicher
New Habit: EDC Process

Primary Investigator

Source Document

CRC
- Run edit checks upon entry
- Resolve queries immediately

CRFs

Master Clinical Data DB

App Server
- Create edit checks
- Data Review
- Enter queries manually

Web Server

CDM
- Data Review
- Enter queries manually

CRA

Internet

Source Verification

CRA

Site

Sponsor
• Old Habits:
  – Author each protocol as an individual text document
  – Collect data on paper source documents and CRFs

• New Habits: Begin with the end in mind
  – Structured protocol drives EDC system setup and analysis plans
  – Standard metadata represented in a clinical data warehouse

• Collect data electronically at source
  – Avoid transcription

• Always use common data standards

Drug Information Association  www.diahome.org
Old Habit: Data Silos for Each Study

- Disparate workflows, systems and views
- No holistic view of studies or clinical program
- Inability to combine data across studies

Source: Jagath Wanninayake
Old Habit: Disposable Data

Standards-based Metadata Repository and Data Warehouse Promotes Re-use
• Standards-based data promotes pooling, comparison and reuse
• Collect once, use many times
• Treat all research data as a critical asset
The Convergence of Healthcare and Clinical Research

- **Personalized Healthcare**
  - Translational Med
  - Targeted Therapies
  - DNA chemistry and advanced technology
  - Increased regulation and efficacy standards
  - Blockbusters and mass-production of novel drugs

Patient Care and Disease Mgmt

- Analytics
  - Pharmacovigilance and Risk Mgmt
  - Safety at Point of Care
  - Electronic Data Capture
  - Electronic Medical Records
  - Paper based Records
  - Paper based Systems

“Evidence Based” Healthcare

“Managed” Healthcare

“Precision” Healthcare

“Trial and Error” Healthcare

LIFE SCIENCES

HEALTHCARE

Source: Oracle Health Sciences

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Some provider functions move from enterprise to market, e.g. IRB workflow, Patient consent, common licensing practices

Source: Oracle Health Sciences
CDISC Structured Protocol Model
CDASH forms with ODM Transport
Retrieve Protocol for Execution (RPE) Profile
Retrieve From for Data Capture (RFD) Profile
CDISC ODM Standard messaging and archive
New Habit: Control & Reuse Data

Oracle’s Healthcare Platform at Moffitt
Single Platform, Multiple Uses

Clinical and Operational Analytics (At Moffitt)

Translational Medicine
(At Moffitt and collaborative academic partners)

Care Management
(Moffitt and affiliate patients)

Enterprise Healthcare Analytics

Clinical Development
(With Pharma R&D partners)
Conclusions

• China has a rare opportunity to look forward, rather than back, by applying new technologies to its rapidly growing clinical research and development activities

• Some principal opportunities include:
  – Build a 21st century IT infrastructure: use shared resources in the cloud and mobile technologies.
  – Become digital – avoid paper wherever possible
  – Embrace standards to enable interoperability and reuse
  – Treat all research information as a valued asset – gain control of healthcare/research data from the beginning
  – Bet on the convergence of healthcare and research

• To realize the vision, we will need collaboration and support among sponsors, regulators and vendors.
“The fundamental difference between a dog and a human being is simple: When you point with your finger, the dog looks at the tip.”

--Nicholas Negroponte
Rethinking Clinical Research with a Clean Slate

Thank you.

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