AstraZeneca’s

Road to CDISC Implementation

(Washington DC CDISC User Network Presentation 2008-04-09)

Dan Godoy
Information Strategy Director
AstraZeneca
Outline

- Understanding AstraZeneca
- The road to CDISC
- Clinical Development Information Strategy
- Our Current status
- Lessons Learned
Understanding AstraZeneca
Understanding AstraZeneca (1/5)

- Merger of two Companies ~8 years ago
  - Swedish Astra (including US Operations)
  - UK Zeneca (including US Operations)
- Multiple [formerly] independent sites
  - 1 in Wilmington, DE
  - 2 in UK (Alderly Park, Charnwood)
  - 3 in Sweden (Sodertalje, Molndal, Lund)
- Many platforms
  - UNIX
  - Windows NT
  - Windows PCs
- Multiple data collection/analysis systems
  - CROs
  - Internally developed
  - Safety, Clinical, PK/PD, etc.
Understanding AstraZeneca (2/5)

- Multiple Therapeutic Areas
  - Oncology
  - GI
  - CV
  - Pain & Infection
  - Inflammation
  - Neuroscience
  - Respiratory

- Multi-matrix Organization
  - Functional
  - TA
  - Drug Project
  - Improvement Initiatives
  - Commercial

- Multiple Org. charts
  - Regional & Global
  - Regional vs. Central
Understanding AstraZeneca (3/5)
Understanding AstraZeneca (4/5)

- **Multiple Cultures**
  - Swedish
  - UK
  - US

- **Multiple Histories**
  - Former Astra companies
  - Former ICI/Zeneca
  - Former Astra-Merck

- **Multiple “languages”**
  - Swedish
  - UK
  - US
  - Astra
  - Zeneca
Understanding AstraZeneca (5/5)

- In the end, a great integration but with
  - Lots of systems to integrate
  - Plenty of redundancies (e.g., processes, tools)
  - Mixed accountabilities (e.g., same process but different responsible function based on location)
  - Many models tried and implemented

- Moving along while delivering Drug Projects

- Strong Standards Organization
  - But most at Project/study level
  - Passionate about standards... just not your standards!
The Road to CDISC
The Road to CDISC (1/2)

- Initial involvement as independent participants on SDS, SEND and ADaM Teams
  - Engaged in many subteams
  - Interacted with other team members
  - Developed network and knowledge base
- Lobbied heavily for formal membership
  - Senior Leadership approached for funding of membership fees
- Developed Awareness & Action campaign
  - Cross-functionally
  - Several layers of leadership
The Road to CDISC (2/2)

- Secured initial CDISC Sponsor fee
  - Managed to keep renewals as a constant budget item
- Slowly increased participation in CDISC teams
  - Lobbied many functional leaders
  - One-on-One benefit-risk discussions
- Dealt with re-organization
  - New opportunities
Clinical Development Information Strategy
Situation today in Clinical Development

- We have fragmented information assets; accessing and reusing scientific data and information across projects is becoming increasingly difficult.
- Current information infrastructure is not fit to be able to exploit clinical data & information in an effective way.
- Information sharing takes place but in an inconsistent way and processes for sharing data and information are not clear and consistent.
- In short - Clinical Development lacks efficient information interoperability, or information connectivity between customers and functions.
Rationale for CDIS

- Establish a consistent strategic direction & coordination of Clinical Development’s Technical Information
- Achieving *information interoperability* and thereby maximizing the information assets of Clinical Development
- Development of a new technological platform & new ways of working that improves our management of information
- Improve coordination and alignment of on-going information management initiatives

(*) Technical Information here is defined as information or data created, received or managed by Clinical Development that could be shared internally and may eventually be exchanged with a regulatory agency or associate, throughout its full lifecycle, including regulatory status information on submissions and products.
Perspective on the CDIS
A focused view of information with three key dimensions

Impact and interface
Three principal components of CDIS

Implement new processes & principles for simplifying information sharing & exploitation

Evaluation model to ensure efficient, valid & relevant implementation of the strategy over time

Develop a shared resource for information services & supporting interaction between functions to improve exploitation of information
What are the benefits of CDIS?

Short term (1-2 years)

- Improved information sharing by a shared language, transparent process, simple principles and roles
- Improved information exchange between functions & projects in Clinical Development
- More effective data extraction for clinical studies
  - e.g. providing effective navigation, pooling & retrieval of clinical data and information for various purposes
- Easier access and retrieval of information to support key projects
- Significantly enhance the information flow between Discovery and Clinical
What are the benefits of CDIS?

Long-term (3-5 years)

- Enhancing the speed of delivery of study data
  - from capture to a shareable & structured format
- Significantly enhanced analyses
  - e.g. global capability of investigation of adverse events in an entire therapeutic class
- More effective clinical research capabilities
  - e.g. by providing tools for text mining and visualizing of clinical data
  - add enhanced ability for adaptive clinical trials
- More efficient study design
  - e.g. potential to not only eliminate "unnecessary" studies but stop studies sooner
- Capable of exploiting & including other future information sources and securing information transparency
- Enhance efficiency by providing a new “global source data” platform for Drug Safety
- Streamline processes for authoring & reuse of text
AZ Current Status
AZ Current Status (1/4)

- Created a Standards Governance Organization
  - Managing internally-developed standards
  - Incorporating external standards with guidance from AZ CDISC Network

- Implementing a Data Warehouse
  - Modeled after Janus (& Information Model)
  - Also developing Metadata & Standards Repository (the brains)
  - Providing DEFINE.XML capability
  - Integrating all of our data systems around warehouse

- Implementing SDTM
  - Mapped all of our CRF modules to SDTM
  - Created/still creating SAS programs to transform CRF datasets → SDTM
AZ Current Status (2/4)

- **Implementing ODM**
  - For all external data transfers to AZ
  - For all data exchanges between internal systems

- **Exploring SEND**
  - Learning impact to existing data domains
  - Evaluating compatible tools

- **Learning ADaM**
  - Incorporating it into existing standards

- **Exploring Controlled Terminology**
  - Participating in CT Team
  - Evaluating how to best integrate with internal CT
AZ Current Status (3/4)

- **Heavier CDISC engagement**
  - Active members of Industry Advisory Board
  - Active members in **all** CDISC teams
  - Participating in 4 Pilots w/ FDA-CDISC
    - ODM CRF
    - ADaM-SDTM Part II
    - PGx
    - SEND
  - Participating in CDISC initiatives
    - CDASH
    - Pharmacogenomics
    - CV
    - Oncology (may need new resource)
AZ Current Status (4/4)

- Heavier CDISC engagement (cont.)
  - Leading and/or participating in CDISC User Networks
    - Global User Network (leading)
    - Delaware Valley (leading)
    - English Language (participating)
Lessons Learned
Lessons Learned (1/3)

- **CDISC needs a Champion**
  - Not necessarily an expert in all things Clinical
  - One person who can secure a Sponsor
  - One person who can rally and build alliances
    - With functions
    - With leaders

- **CDISC message needs customization for**
  - Leaders (Cost & Benefits)
  - Drug Projects (Benefits over existing standards)
  - Functions (efficiencies & collaborations)
  - Regulatory Affairs (compliance)
  - IS/IT (compatibility & interoperability)
Lessons Learned (2/3)

- CDISC needs cross-functional buy-in & collaboration
  - Finding synergies and efficiencies (Value Chain)
  - Describing impact to “my daily job”
  - Benchmarking

- CDISC is communication
  - Constant messaging
  - Raised awareness of external training opportunities
  - Develop internal training opportunities
  - Up-to-date status of external progress

- CDISC requires to break down some natural “walls”
  - US vs. ROW
  - FDA only
Lessons Learned (3/3)

- CDISC requires commitment
  - To participate externally
  - To lead internally
  - To identify and deploy functionally-aligned representatives

- CDISC requires skillful leveraging of available resources
  - Case Studies and presentations available on CDISC Website
  - Contacts, teams, User Networks

- CDISC Requires clear connection to other key initiatives
  - eCTD implementation
  - CRIX
  - Critical Path
  - Electronic Health Records (EHRs/EMRs)
Q&A