Enabling Efficient Electronic Regulatory Submissions for Medical Devices Using CDISC Data Standards

Kit Howard, MS, CCDM, CRCP, Principal, Kestrel Consultants
in collaboration with
Laura Fazio (DePuy Orthopaedics), Daniela Luzi (CNR-IRPPS), Parag Shiralkar (eClinicalSolutions), Jennie Tedrow (Boston Scientific), & Rhonda Facile (CDISC)

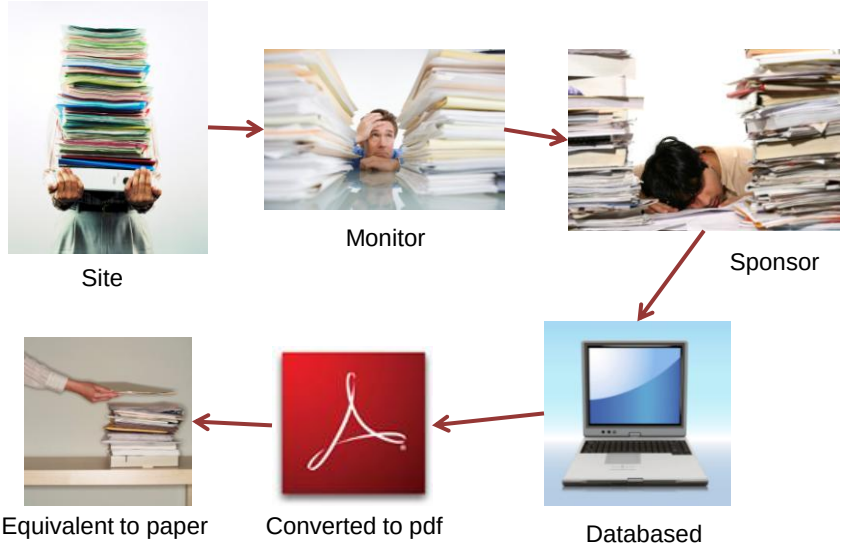
Outline

- Current State
- CDISC as Part of the Solution
- CRF Analysis
- Implications / Benefits
- Conclusion

What Are Medical Devices?

- Diagnostic machines and tests
- MRI and other imaging machines
- Software to run the machines
- Orthopaedic plates and screws
- Blood pressure monitors
- Latex gloves
- Birth control (IUD)

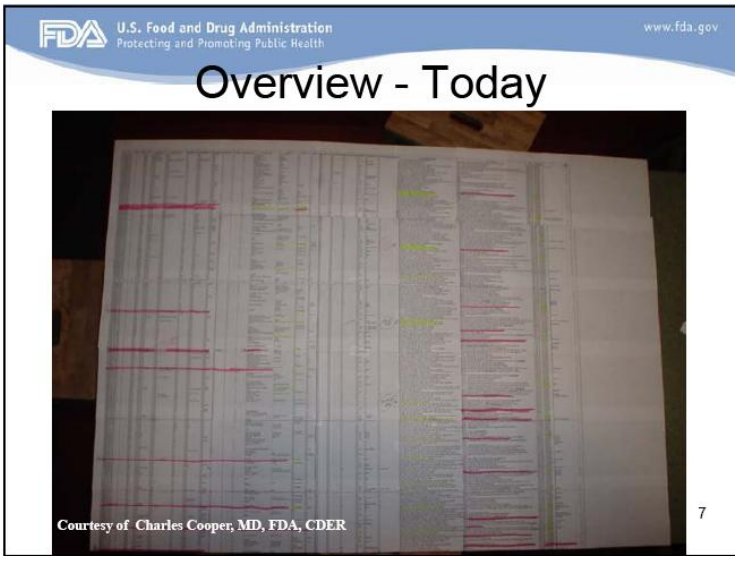
Current State: Medical Device Data



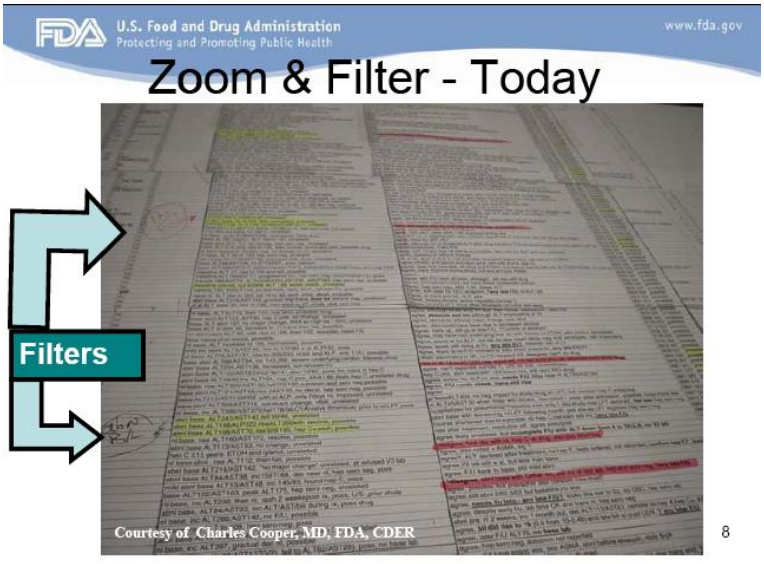
Summarizing/Analyzing the Data

Slide courtesy of Teresa Mullin, FDA, "Developing a CDER/CSC Data Standards Plan," DIA/FDA Meeting On Computational Science, Mar 2010

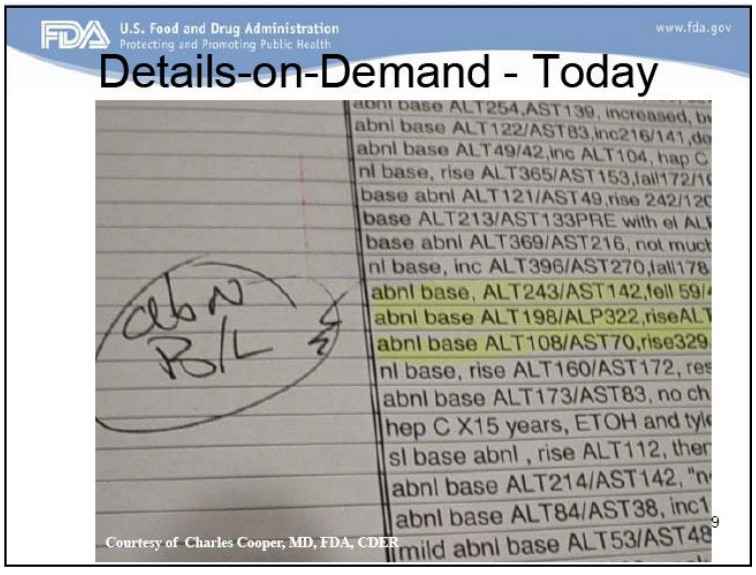
Assembling the Data



Drilling Down into the Data



Analyzing the Details



Part of the Solution

SDTM

CDISC Snapshot

- Global, open source, consensus-built, multi-disciplinary non-profit organization
- Established industry standards for the electronic definition, acquisition, exchange, submission and archiving of data for regulated research
- Includes clinical, -omics, selected pre-clinical

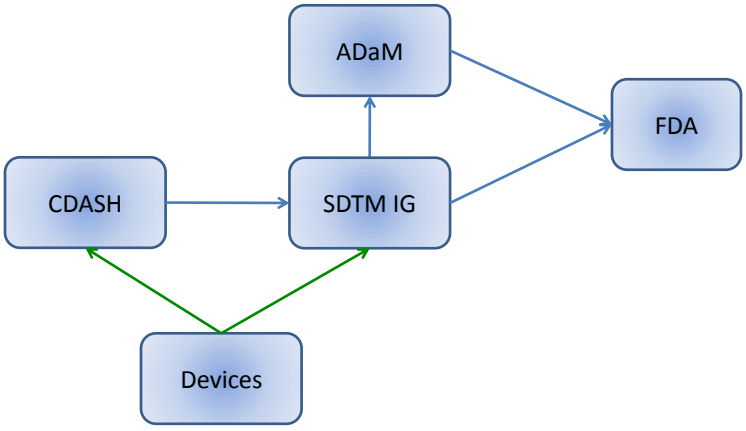
CDASH Definition, Purpose & Scope

- CDASH: A set of *content standards* for a basic set of global industry-wide data collection fields to support clinical research
- System-independent, open source, free
- Covers both paper and electronic data capture
- Not CRF layouts
- Sponsored by CDISC

SDTMIG

- Study Data Tabulation Model Implementation Guide for Clinical Research
- SDTMIG is the electronic data regulatory submission standard that will soon be required for all NDA & BLA data submissions (and all supplemental submissions)
  - CDER already accepts data in SDTM format
  - CBER expects to start in May 2010
  - CDRH is expressing significant interest, has formed a standardization committee internally and is participating in the CDISC Medical Device initiative

How It All Fits Together



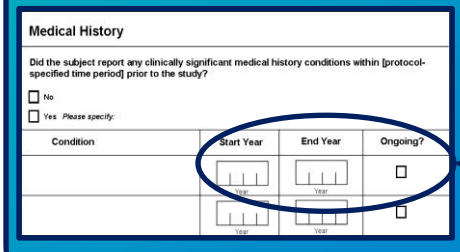
Medical Device CDASH Project

In 2009, CDISC-AdvaMed Device team members compared a selection of common device CRFs to the CDASH standard to determine whether CDASH could be used for device studies.

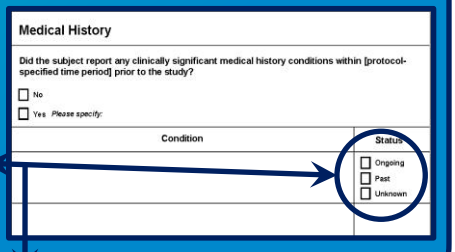
Methodology

- Collected 138 Device CRFs
- Compared to Drug CRFs
- Identified differences
- Recommended solutions

CDASH Sample CRF



Device Sample CRF



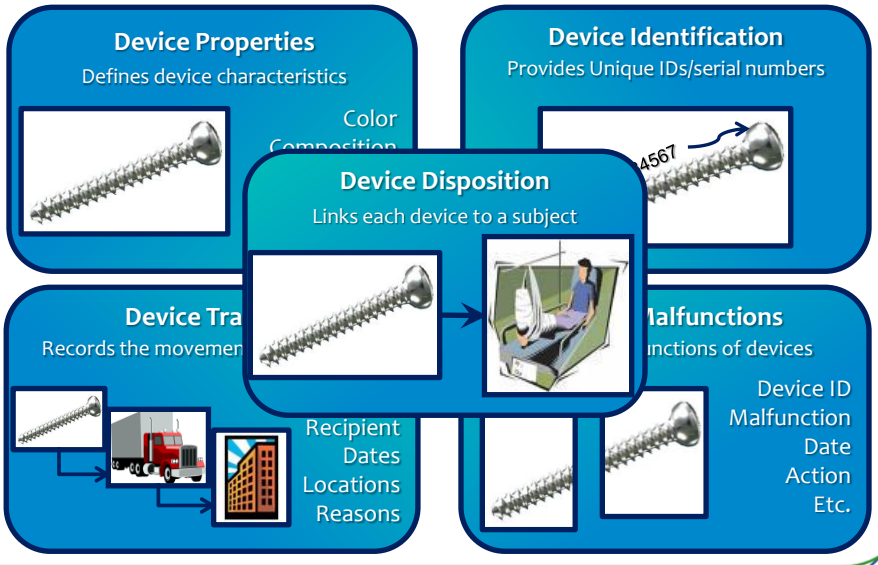
CDASH format provides greater precision.
Recommend CDASH.

Most Device Needs Met by CDASH

Additional Device Need	CDASH Response
Associate 1 AE with >1 device	• Also useful for studies with >1 drug • CDISC developing a solution
Assess AE Action Taken & AE Relationship to >1 device	• Also useful for studies with >1 drug • CDISC developing a solution
AEs for operators, not just subjects	• Needs further investigation • Can be handled using existing structures
Protocol deviations for instruments, not just subjects	• Adding Device ID will resolve this issue
Terminology: use same words in different ways	• Action taken with respect to drug vs. action taken to treat AE • Disposition = subject status vs. location of device

16

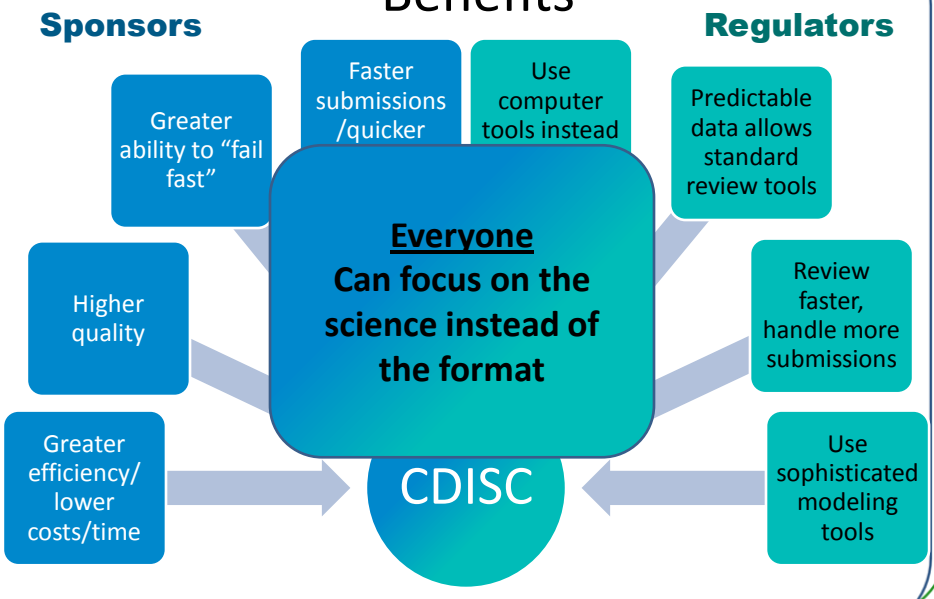
5 New Domains



Implications

- This will require changes for both sponsors and regulatory authorities
- Sponsors: change field names, data structures, possibly questions asked
- CDER: developed several tools to facilitate usage
- CBER: going on-line this year
- CDRH
  - can leverage the work done by the others and implement more easily
  - Will facilitate joint submissions with CDER/CBER

Benefits



Conclusions

- Data standards for regulated research are in various stages of development and implementation
- CDRH and medical device companies are latecomers who can benefit from prior work
- CRF analysis demonstrated that, while there are differences between drugs and devices, they are manageable
- Continuing this development will require changes but will be beneficial to all

References & Contact

References

- CDASH Standard, www.cdisc.org
- CDISC Controlled Terminology: www.cdisc.org
- SDTM IG Standard, www.cdisc.org
- Devices & Drugs: More in *Common Than You Think!* Poster, Rhonda Facile & Kit Howard, CDISC European Interchange, London, 2010

Contacts

- For questions related to this presentation and the Medical Device project: Kit Howard, kit@kestrelconsultants.com
- For questions related to CDISC: Kit Howard or Rhonda Facile, rfacile@cdisc.org

Thank You

- CDISC Medical Devices Team Leaders
  - Kit Howard (Kestrel)
  - Carey Smoak (Roche)
  - Rhonda Facile (CDISC)
  - Fred Wood (Octagon)
- Medical Device CRF Analysis Team
  - Daniela Luzi (CNR-IRPPS, Italy)
  - Jennie Tedrow (Boston Scientific)
  - Laura Fazio (DePuy Orthopaedics)
  - Parag Shiralkar (eClinical Solutions)