Implementing CDISC standards in an Early Phase CRO – Successes and Challenges

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PURPOSE

To increase efficiency of production processes, and accelerate clients' delivery time by harmonizing our data processes with those of the Clinical Data Interchange Standards Consortium (CDISC).

INTRODUCTION

Phase 1 units are high-paced units that require the use of event-based tools to collect data, instead of the form-based tools typically used in later stage studies, creating challenges in the CDASH implementation. Another challenge is that the various clinical units have data collection tools already fine-tuned to their own processes and priorities. The present poster will describe important components recommended in order to facilitate the process of integration of the CDISC data standards efficiently, and how to measure its success.

This initiative involved the optimization of SDTM and ADaM standards, already in place throughout Algorithme Pharma, as well as the implementation of CDASH standards. In order to be successful, the CDASH processes had to be implemented to work with each of the data capture systems already in place; and allow for accurate and efficient mapping and documentation, while accommodating client preferences.

ABOUT ALGORITHME PHARMA

Algorithme Pharma is a full service early stage CRO with 2 specialized clinical units (Canada and U.S.A.); and since 2013, a sister company, Vince & Associates Clinical Research, with its own clinical unit. We provide comprehensive early stage clinical drug development services in Phase I/IIa, including the necessary support services required in this critical stage of drug development.

All three sites have different data collection processes, with a centralized data management (paper and electronic CRF) and biostatistics unit.

Our partnerships for multi-site studies and with local hospitals increase access to patient populations in key therapeutic areas of research, as well as to an extended experienced network of clinical research experience.

Algorithme Pharma – AN ALTASCIENCES COMPANY

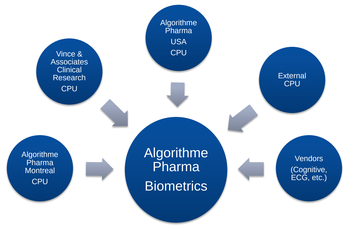
Vince & Associates CLINICAL RESEARCH – AN ALTASCIENCES COMPANY

Algorithme Pharma USA – AN ALTASCIENCES COMPANY

- **Since 1992:**
  - BE / 505(b)(2) / Phase 1
  - Special populations (hepatic, renal impaired)
- **Sister Company, joined 2013:**
  - Phase 1 / 2
  - Substance abuse, sleep, etc.
- **Joined 2014:**
  - BE / 505(b)(2) / Phase 1
  - Dermatology, etc.
- **Partnerships:**
  - Multi-site studies
  - Local hospitals

Wide range of study types:
Phase I/IIa • Bioequivalence • Bioavailability • 505(b)(2)

New challenges:
- Multiplication of vendors: safety labs, cognitive assessments, ECG monitoring
- Significantly different data collection processes
- Sponsor expectations vs. CDISC deliverables



METHODS

Data collection flow consistent with CDISC standards was developed in collaboration with the clinical units. The implementation was done sequentially, one clinical unit at a time, to identify and resolve issues, and fully document the process. SDTM processes were optimized in parallel, to benefit from the gains in efficiency provided by the CDASH implementation.

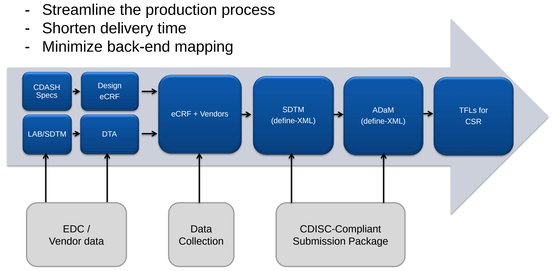
Standardize:
- Data collection : CDASH, LAB
- Data processing (mapping, tabulation, analysis): SDTM, ADaM

TARGET

- All data sources
- All clinical units (in-house and external)
- Vendors

OBJECTIVE

- Increase data quality and traceability
- Streamline the production process
- Shorten delivery time
- Minimize back-end mapping



TEAM

Included members from each functional area and unit:

- Study Manager (one per clinical unit)
- Data Manager
- Statistical Programmer
- Data Entry Technician
- Biostatistician

MANDATE

To evaluate:

Resources	Systems	Processes
- Do we have enough staff? - Do they have enough training?	- Are our systems adequate? - Are they used properly?	- Need to be modified? - Need to create additional?

RESULTS

Resources
- Additional staff hired
- Additional training required

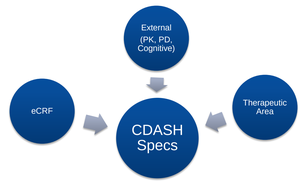
Systems
- Adequate
- Some adjustments needed

Process
- Data collection: source document creation (source vs CRF, SOPs)
- Data processing: submission package and TFLs

CDASH
- Integrated for all in-house clinical units
- Standards for external units
- Review of all CDASH domains used
- Standard CRF developed

SDTM
- Complete integration
- Detailed process for two EDCs used internally
- Easily customizable for any EDC
- Included CDASH domains identified
- Specs defined in parallel with CDASH specs
- Mapping specs from CDASH to SDT created
- Development of define-XML specifications

ADaM
- Specs defined in parallel with SDTM specs
- Mapping specs from SDTM to ADaM created
- Development of define-XML specifications



SUMMARY

CHALLENGES

- Protocol harmonization
  - Sponsor provided
  - Different types of studies
- Data Collection
  - Work to be accomplished varied significantly
  - Easier to implement changes for Phase I trials
- Data Processing
  - Considerable impact of CDASH specifications on SDTM
  - Data extracted from some EDC far from “CDISC ready”
  - Vendors do not all comply to CDISC standards
- Requires new way of thinking and working
  - Increases dependencies across groups
  - End-to-end perspective of data flow
- Change management
  - More complex than it seems
  - Significant effort
  - Require business process changes

SUCCESSES

- Source document standardization
  - Less data entry errors, less queries, less missing data
  - Data entry is done more rapidly
  - Database lock process is more efficient
- Standard mapping rules to SDTM
  - Requires significantly less customization
- TFL creation process
  - Flexible, customizable
- Adaptive, efficient process
- Real-time savings

CONCLUSION

The implementation proved that CDISC standards can be very helpful to increase efficiencies in the collection, analysis and submission of clinical data. Standardization of data collection in clinical units has helped reduce database lock time, and data entry errors. The use of SDTM and ADaM for analysis and submission has streamlined the biostatics production process, and has decreased the production time.

DISCLOSURE

The author of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

Pascal Guibord: Nothing to disclose