MAXIMIZING THE VALUE OF CLINICAL TRIALS DATA: A COLLABORATIVE FRAMEWORK FOR DATA STANDARDS GOVERNANCE FROM DATA DEFINITION TO KNOWLEDGE MANAGEMENT

PharmaSUG Single Day Event
Using Standards, Even for Non-Standard Needs
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Welcome
Themes for Maximizing the Value of Clinical Trials Data

1. Standardized Data **ARE** Very Valuable. Non-Standardized Data are less valuable over time.

2. Standardized Data are not just for regulatory submissions. Needed for Life-cycle Development

3. Corporate Data Standards Governance at Top of an Organization Yields Significantly Greater Value
Data Standards Implemented across A Drug development Program can reduce the cost (both financial and time) Required to develop a compound.

~ 250 to 300 Million USD
Where are Data Standards Applicable?

- Target ID
- Disease Biology
- Medicinal Chemistry
- Assay Dev.
- HTS
- Pharmacology
- Pre-Clinical Dev.
- Animal Tox
- ADME
- Rx Delivery
- Phase I
- Safety
- PK PD
- (≈100)
- Phase II
- Dose Finding
- Initial Efficacy
- Safety
- (≈300)
- Phase III
- Efficacy
- Safety Trials
- Large Pop.
- (≈1000)
- FDA Review
- EMEA Review

Formulation → Pilot Plant → Stability Testing → Manufacturing

At all stages of development

Indefinite ~3 yrs ~3 yrs ~1 yr ~2 yrs ~3 yrs ~1.5 yrs

Approximate Time (Years)
Implementation of Data Standards MUST Start with an IND (IMPD)

Include the SDSP Into Development Planning

Target Product Profile

Chemistry Manufacturing Controls
Pre-Clinical Development
Toxicology
Legal
Regulatory
Drug Safety
Clinical Development
Marketing

Development Plan
Impact of Data Standards on Life-Cycle of a Compound ...

Corporate Governance: Data Standards

- Clinical Trials
- Integrated Data
- Publications Meta-Analysis
- Regulatory Submissions
- Market Access
Standardized Data Supports Market Access........

- Pricing and Reimbursement
- Account Management & Managed Markets
- Health Economics & Outcomes Research
- Analytics & “Real World” Clinical Effectiveness Information
- Public Government & Advocacy

Market Access
Individual Data Items (Standard or non-Standard)

Individual Data Items (Standard or Non-Standard) decrease in value to a development program over time. They represent a static assessment or a sample at a point in time.
Non-Standardized Data Over Time

The value of clinical trials data occurs when it is aggregated together (populations) to examine populations of individuals. Non-standardized data have less value due to higher operating costs.
Standardized Data Over Time

The value of clinical trials data occurs when it is aggregated together (populations) to examine populations of individuals. Standardized data have greater value due to significantly lower operating costs.
Value Difference: Standardized v Non-Standardized Data

Value difference occurs with both real operating costs to form data into the aggregate and in utility of information for multiple uses in the development lifecycle.
Quick Example .... Chronic Pain Rx

• 12 Study NDA/PLA Application (Phase I-III)
• CDISC SDTM/ADaM Implemented for
  – 1 Pivotal Phase III Study
  – 1 long term Safety Follow-up Study
• 10 Studies with NO Data Standard
• Time and Cost to Standardize for Submission
  – 10 Months to Standardize
  – $1.8 million in contractor costs
  – Delay from planned submission date: 13 months
• Estimated lost revenue from sales: $18 million
Clinical Trials Data Standards Governance

- Standards Organization (CDISC)
- Regulatory Authority (FDA, ICH)
- Corporate
- Project
- Study
- Endpoints
Role of Standards Governance in Synthesis of Clinical Trials Data
Value of Corporate Data Standards Governance

• Reduce Errors and Risk
• Improve communication
• Meet expanding corporate utilization needs
• Reallocate Resources
• Realize Financial Savings
• Improve staff learning curve (onboarding)
• Gain comprehensive holistic view of program
• Improves Review Cycle Time of Regulatory Authorities
Clinical Trials Data Standards Governance

Participate on Standards Development – Leading to improved Clinical Trials Standards

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Governance Leadership at VP R&D (CMO) Level

Enforcement of Industry and Regulatory Standards Impacts All Projects.

Develop and Train all Staff on Corporate Data Standards. Publish and enforce a Corporate Standards Implementation Guide.

Enforce Data Standards Through QA and Regulatory Departments
How to Implement Corporate Data Standards Governance

• Corporate Executives need to be educated that:
  – Data Standards **ARE NOT** Optional for Regulatory Approval in the Largest Pharmaceutical Market in the World.
  – Implementing Corporate Data Standards **will reduce** operating and development costs.
  – Market Access responsiveness for “Data” is significantly Improved. **Time is Money!**
Same Principles and Utility of Data Standards for FDA Review Applies to Corporate Decision Making!

Educate Decision Makers on Value of Collaborative use of Data Standards for Life Cycle Development.
Educating Corporate Executives on the **Economic Value** of Corporate Data Standards Governance will lead to Implementation and Enforcement
Discussion

• What areas in the development and life cycle management of an Rx within a company would benefit from corporate data standards governance?

• What role can we serve to educate corporate decision makers on Data Standards Governance? (Benefits/Risks)

• What role can corporations take in developing standards?

• What are some key issues in educating and enforcing data standards with CROs and other vendors?