Data Transformation

Best Practices for When to Transform Your Data

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SAS in the Life Sciences Industry

2,350+	Life Sciences customers worldwide
100%	of the Life Sciences companies in the Fortune 500 use SAS
45+	countries with SAS customers in Life Sciences
FDA	SAS is the de facto for clinical data submissions

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In collaboration with

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Life Science industry SME,
Senior Solutions Architect SAS

Mira Shapiro
Data-Scientist

Panel discussion at CDISC US Interchange
October 17th

CDISC Requirements

Worldwide

Austin, TX – 30 November 2016 – The Clinical Data Interchange Standards Consortium (CDISC) would like to remind the clinical research community that the FDA Binding Guidance goes into effect next month. Sponsors **whose studies start after December 17, 2016** must submit data in FDA-supported formats listed in the FDA Data Standards Catalog. The current FDA Data Standards Catalog specifies the use of CDISC standards: **SDTM, SEND, ADaM and Define-XML as well as Controlled Terminology**.

The Final FDA Guidance on Standardized Study Data published December 17, 2014 states . . . "After the publication of this guidance, **all studies with a start date 24 months after the publication date must use the appropriate FDA-supported standards**, formats, and terminologies specified in the Catalog (see section II.C) for NDA, ANDA, and certain BLA submissions."

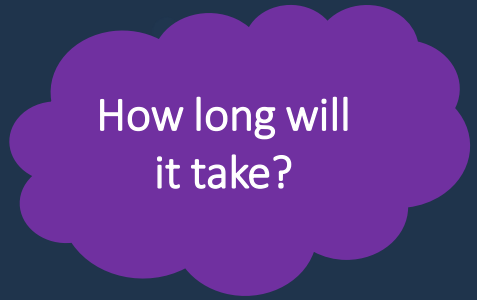
Electronic data submission will be **required from fiscal year 2016 regarding data of clinical studies** (evaluation data) that will be included in the application of new drugs, and those data are expected to be submitted **based on CDISC standards such as SDTM and ADaM**.

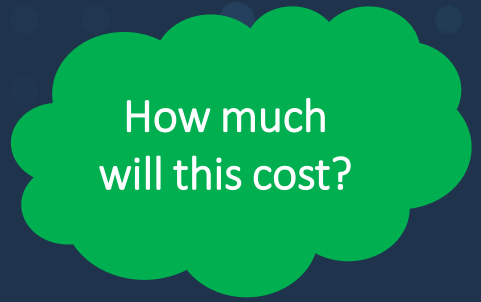
If submitted until 2020 it has to be in CDISC format. **From 2020 onwards submission in CDISC format required**

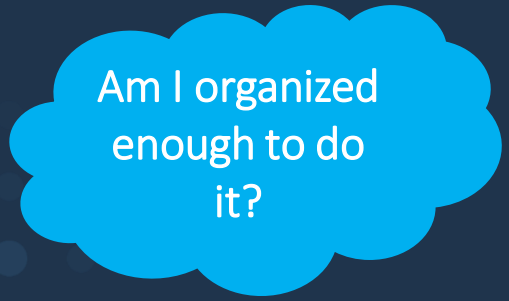
EMA referenced CDISC in a draft guidance on data transparency

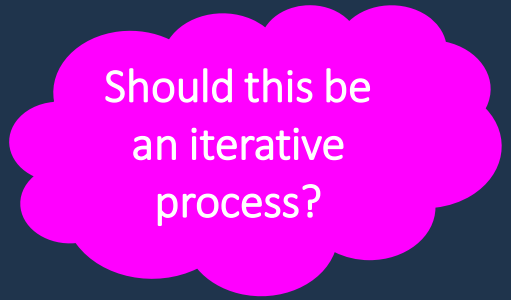
- Reference was removed from final guidance
- EMA focuses more on transparency

When to transform the Data : Topics to Consider

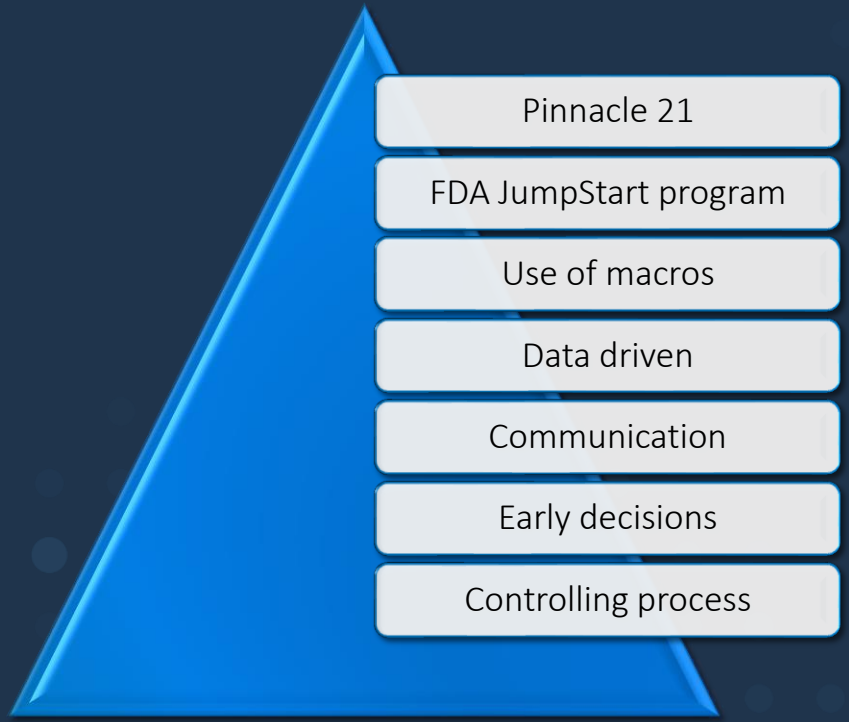






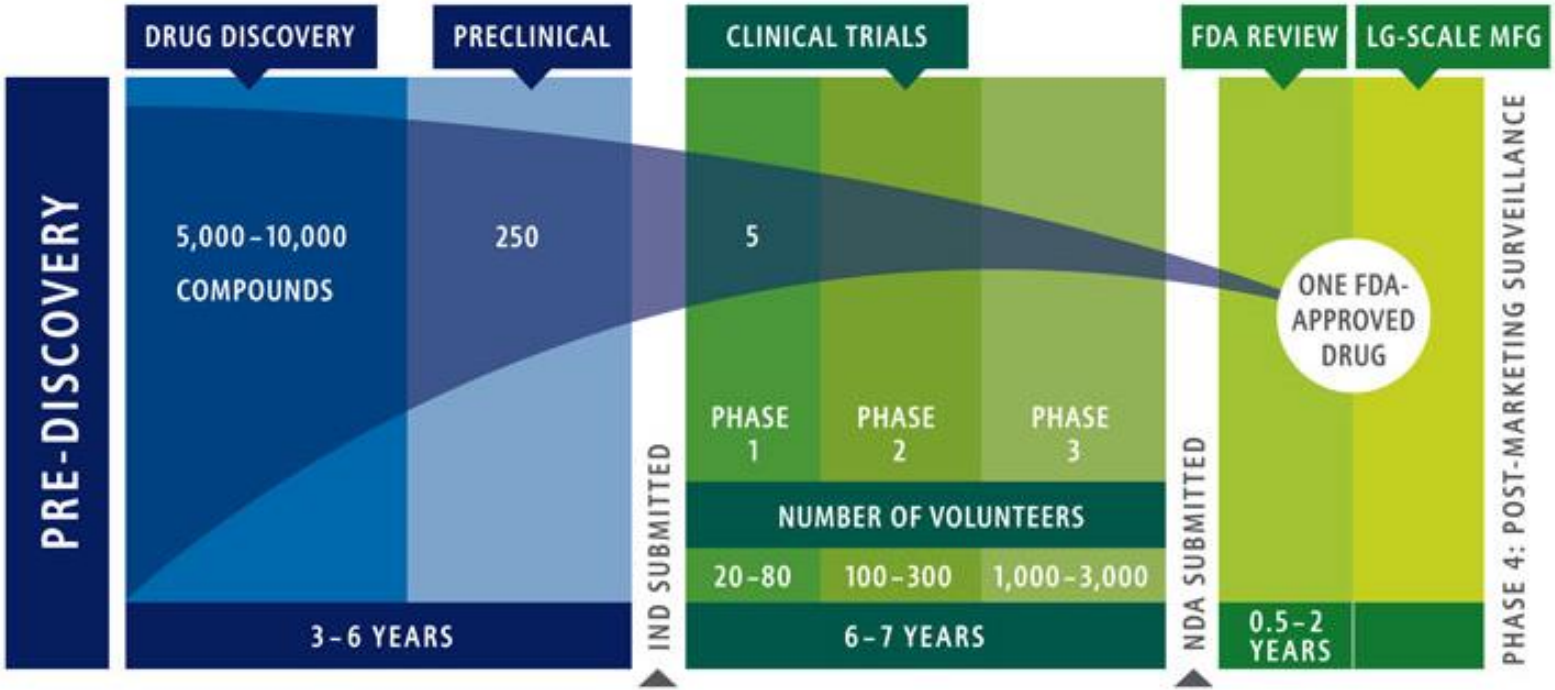


Considerations : Think about cost, expertise, time



Challenge: Drug Discovery and Development

A long and risky road



Source: Pharmaceutical Research and Manufacturers of America

The Beginning: *Before the 1st Patient In*

Data

Resources

Processes

- Proactive with any changes
- 75% of data study is standard
- Mistakes caught earlier
- High resource availability
- CDISC Expertise
- People used to use Standards
- Programs aligned with standards
- Data collection close to CDASH
- Diagnostic can be run earlier

- More expensive – shift priorities
- Investigators still comment CRF
- If no SOPs, need to be completed early
- Trust and lines of communication

During: *While Patients enrolled & data collected*

Data

Resources

Processes

- More knowledge of specifics
- Data Format stable
- Easy changes to transform. code
- Requirements changes reflected in building of domains, tables & documents

- Reinventing the wheel
- Extra expense: extern.submission

Data

Resources

Processes

At the End: *Last patient out; ready for submission*

- Last minute changes difficult to map & need quick decisioning
- More mistakes if trying to retrace steps
- Need to make metadata changes
- Time is of the essence to submit
- Unavailability of resources
- Need CDSIC expertise fast
- More error; more difficult to QC
- Starting from scratch at the end
- Less efficient / More reactive

- Any data anomalies : shown up
- Complete requirements knowledge, data inconsistencies
- More time to formulate SOPs
- Lower cost if passing to external

sas

Summary

"Start With The End In Mind"

- The earlier you start, the optimum data quality should be
- **Warning : less flexibility when you do it so early**

- There is more CDISC expertise required at start
- Need more governance
- **More programming at the end**

- This should be a company strategy with SOPs in place
- The model-driven approach for CDISC standards governance and enhanced study metadata management drive efficiency from study setup to submission.
- **Communication in case it won't be approved: no need to use CDISC standards**
- **Depending on company types (Big Pharma, Start Up, CROs) strategies can vary**
- **Easier to start if data exchange with partners, collaboration in drug discovery**

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Answer the few questions

Thank You

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