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Single Day Event

Clinical Data Strategy and Data Stewardship to Manoeuvre the Increasingly Complex Data and Technology Landscape in Clinical Trials

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- Clinical Data Stewardship to Maneuver Data Standards & Data Strategy

The following are the experiments.

On the 20th of *May* 1747, I took twelve patients in the ſcurvy, on board the *Saliſbury* at ſea. Their caſes were as ſimilar as I could have them. They all in general had putrid gums, the ſpots and laſſitude, with weakneſs of their knees. They lay together in one place, being a proper apartment for the ſick in the fore-hold; and had one diet common to all, *viz.* water-gruel ſweetened with ſugar in the morning; freſh mutton-broth often times for dinner; at other times puddings, boiled biſcuit with ſugar, *&c.*; and for ſupper, barley and raiſins, rice and currants, ſago and wine, or the like. Two of theſe were ordered each a quart of cyder a-day. Two others took twenty-five gutts of *elixir vitriol* three times a-day, upon an empty ſtomach; uſing a gargle ſtrongly acidulated with it for their mouths. Two others took two ſpoonfuls of vinegar three times a-day, upon an empty ſtomach; having their gruels and their other food well acidulated with it, as alſo the gargle for their mouth. Two of the worſt patients, with the tendons in the ham rigid, (a ſymptom none of the reſt had), were put under a courſe of ſea-water. Of this they drank half a pint every day, and ſometimes more or leſs as it operated, by way of gentle phyſic. Two others had each two oranges and one lemon given them every day. Theſe they eat with greedineſs, at different times, upon an empty ſtomach. They continued but ſix days under this courſe, having conſumed the quantity that could be ſpared. The two remaining patients, took the bigneſs of a nutmeg three times a-day, of an electuary recommended by an hoſpital-ſurgeon, made of garlic, muſtard-ſeed, *rad. raphan.* balſam of *Peru*, and gum myrrh; uſing for common drink, barley-water well acidulated with tamarinds; by a decoction of which, with the addition of *cremor tartar*, they were gently purged three or four times during the courſe.

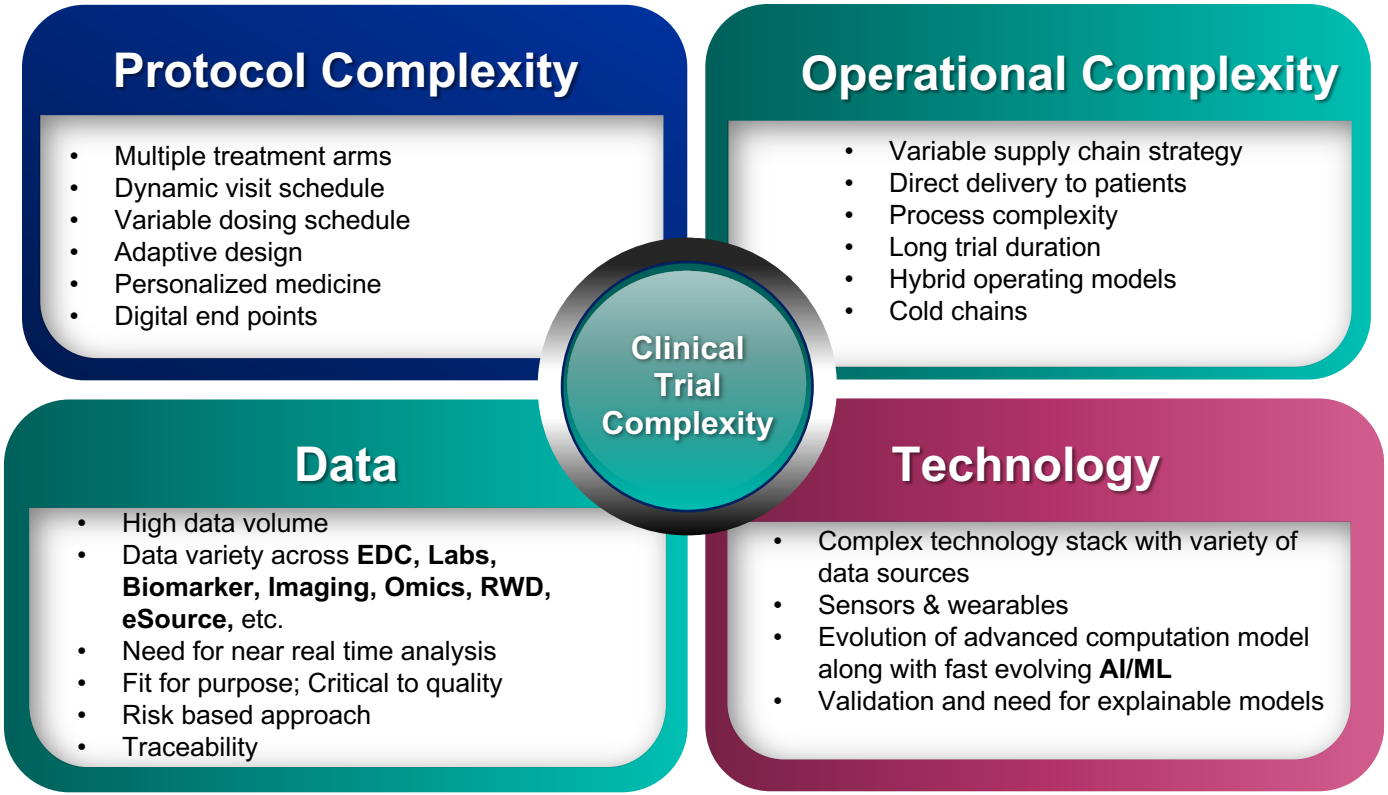
The conſequence was, that the moſt ſudden and viſible good effects were perceived from the uſe of the oranges and lemons; one of thoſe who had taken them, being at the end of ſix days fit for duty. The ſpots were not indeed at that time quite off his body, nor his gums found; but without any other medicine, than a gargariſm of *elixir vitriol*, he became quite healthy before we came into *Plymouth*, which was on the 16th of *June*. The other was the beſt recovered of any in his condition; and being now deemed pretty well, was appointed nurſe to the reſt of the ſick.

James Lind

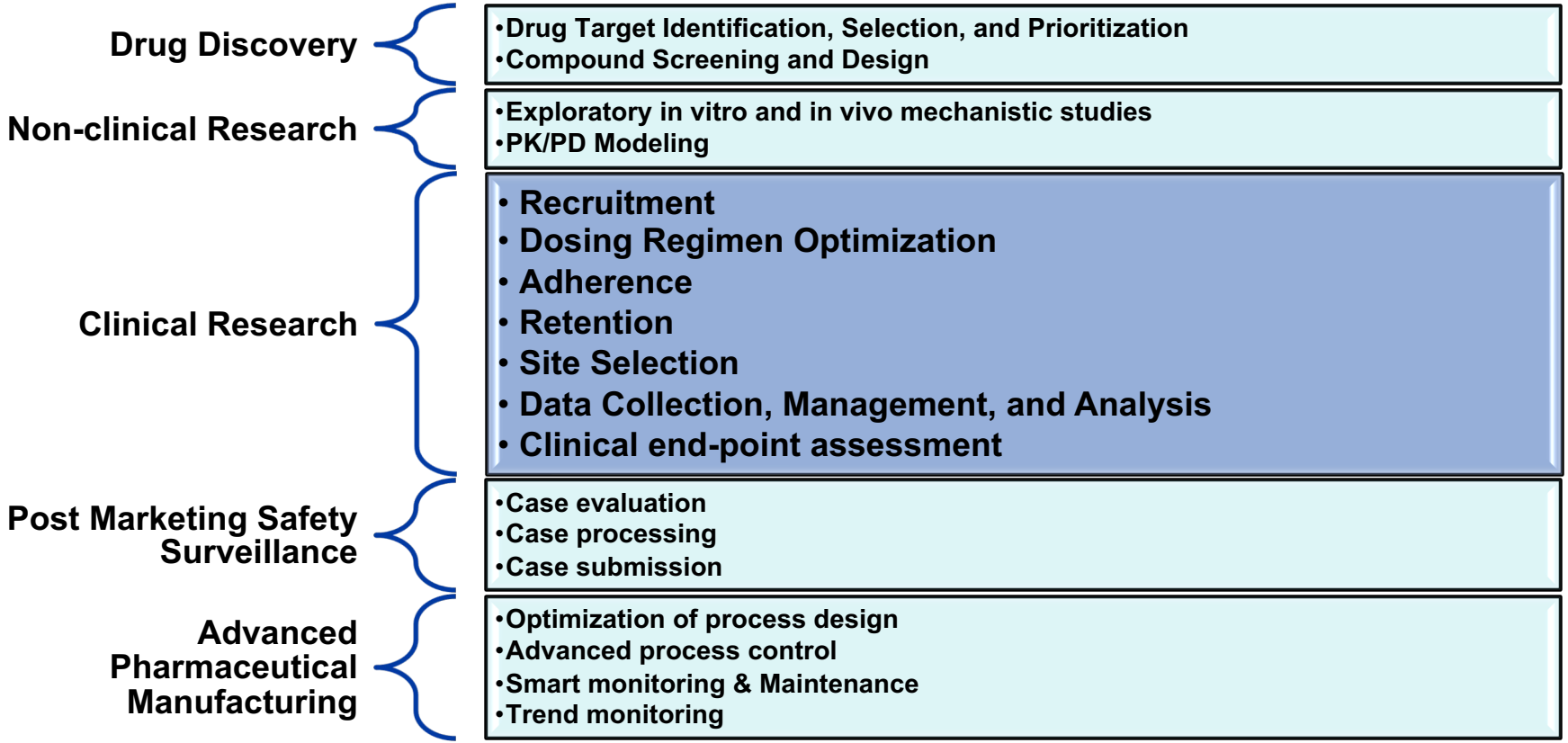
A treatise of the scurvy (1753) - Comparing 6 proposed treatments for Scurvy

A typical Clinical Trial today

Clinical Trial Complexity Drivers



AI/ML: Current Potential Impact Areas



Future Challenges

VALIDITY

PRIVACY

CONCORDANCE

USABILITY

Data Explosion & Propagation

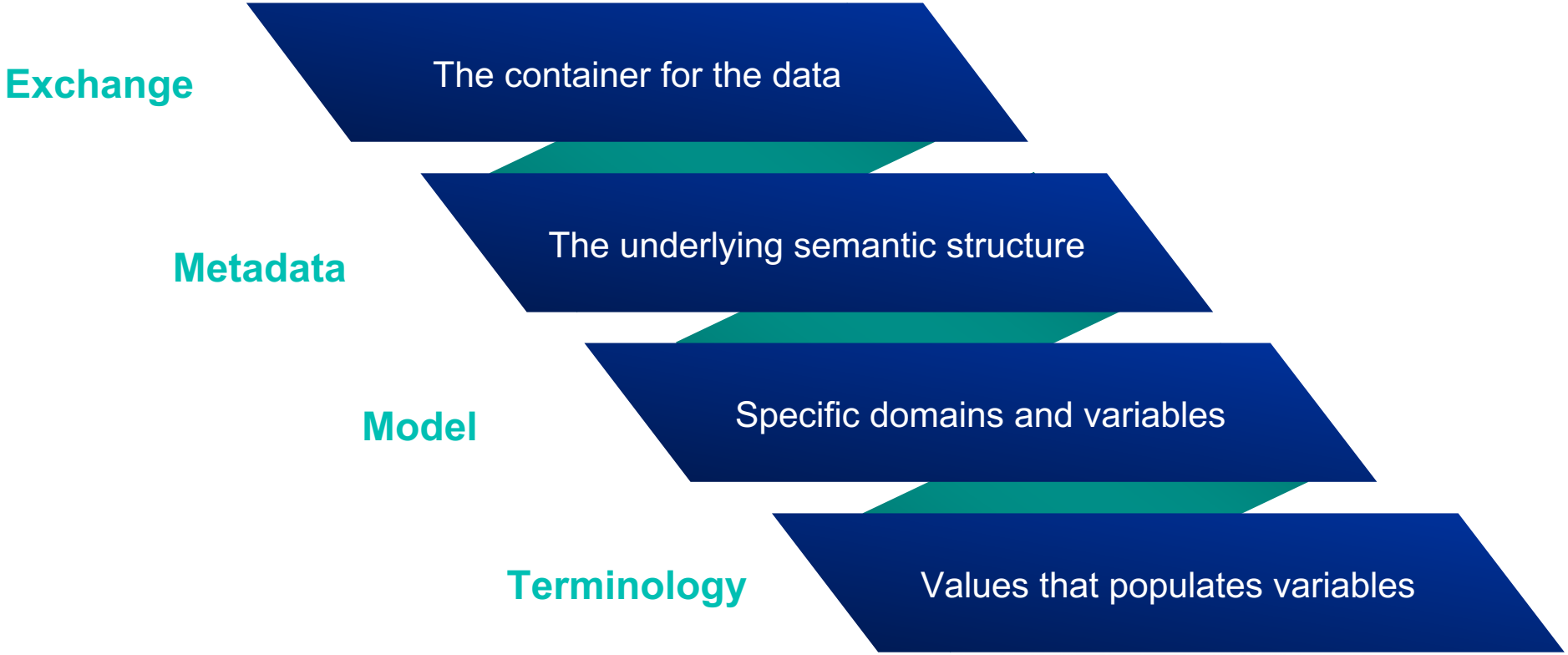
TECH STACK

NEW SOURCE OLD STD

Why Standards?

- Consolidating diverse data sources for improved analysis and planning of studies, enhancing medical insights and disease management.
- Enhancing operational efficiency in data management and analysis.
- Promoting consistent and high-quality data collection in clinical studies, resulting in improved knowledge of compound safety and efficacy.
- Facilitating data traceability and ensuring regulatory reviews are more efficient.
- Establishing a basis for interoperability, aligning with FDA Guidance on electronic regulatory submissions (Feb 2014).
- Enabling seamless integration of clinical studies with Electronic Health Record (EHR) or Electronic Medical Record (EMR) systems in the future.

Layers of Clinical Data Standards



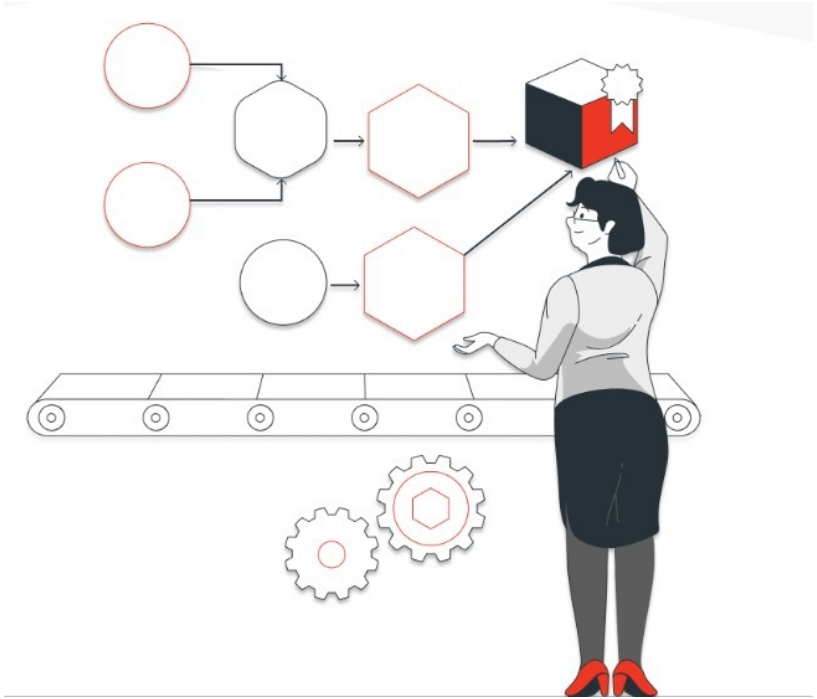
What Are We Trying to Achieve with Data, Technology & Standardization?

- Efficiency through simplification, consistency & reusability
- Reduced cycle time
- Reduction of operational cost
- Quality by design
- Reduce silo and fragmentation approach
- Seamless integration of data and platforms

Barriers to Adoption of standards

- **Strong reluctance to change**
- **Standards not integral part of operational process, rather necessary evil to submit data**
- Slow implementation of ODM and CDASH (Standards and their adoption is much slower compared to the evolution in medical science and technology)
- Clinical research is more complex that 2-D definition of standards (Domain-variable; tabular row-column, etc.)
- **Crossroads of clinical research and health records**
- **Fragmented approach & lack of consensus across line functions for need and extent of data standards**

Evolution from “Data Product” to “Data As a Product” in the Context of Clinical Data Strategy



A data product is a product in which data is the primary facilitator of its main objective.

A data product, in essence, is any platform or tool that analyses data and provides results.

Concept: Data as a product…

Data as a product is all about looking at the data you gather and analysing how it will affect individuals downstream – your data citizens, end users, and others. Viewing data as a product is similar to viewing your shopping components as products.

- Defragmented product ownership
- Fit for purpose
- Definition of data life cycle with usage and lineage
- Program strategy to trial execution

Increased Complexity in Protocol Design Impacts Clinical Trial Performance

[1]Tufts Center for the Study of Drug Development (Tufts CSDD) collected data on trial design elements and clinical trial performance outcomes from 187 protocols provided by 20 companies

Tufts recommendations:

- Limit the number of additional, non-core procedures performed
- Be mindful of the number of internal protocol reviews
- Small reductions in complexity in multiple areas may result in improved performance as much or more than large reductions in a single area
- Controlling the complexity of operational design variables is more effective than focusing on scientific design variables

- **Recruitment rate** ↓
- **Drop out rate** ↑

- **# of substantial amendments** ↑
- **Protocol deviations** ↑

Phase III Protocol Design	2005	2020
# procedures	110	263
# endpoints	7	22
# countries	6	15
# sites	40	104
# data points collected	494,000	3,560,000
Average cost of 1 protocol amendment		**> $500K**

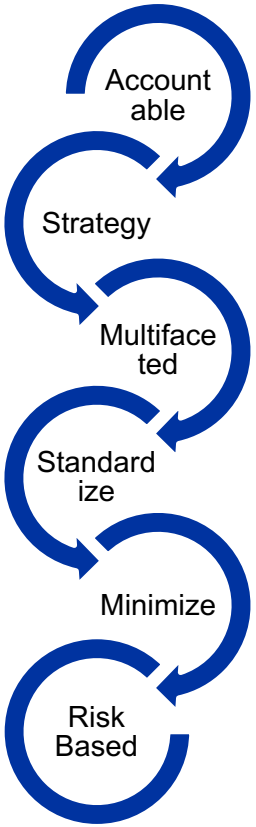
- How proactively do we currently approach these complexities at a strategic level?
- Do we have a Data Steward to manoeuvre and own the clinical data end to end?

1Protocol Design Variables Highly Correlated with, and Predictive of, Clinical Trial Performance (springer.com)

Clinical Data Steward - Role & Impact

Role

- Fit for purpose data collection strategy
- Drive Quality by Design culture
- Risk based approach to data review
- Lean TFL approach
- Standard activist to maximise adoption
- Early building of data capabilities
- Data integration strategy
- De-risking of clinical data flow
- Ensures molecule level & Therapeutic Area level data strategies are implemented at trial level
- **End to end accountability for clinical data as product**



Impact

- Higher adoption of standards
- Early understanding of data flow risk
- Quality by design
- Higher efficiency
- Higher reusability of elements
- Better insight into data-technology integration challenges
- Proactive intervention into clinical data strategy
- End to end ownership of clinical data

A Moment to Pause, Introspect on Nonlinear Complexities & Focus on Defragmented Solutions...

Thank you

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The Global Healthcare Data Science Community

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