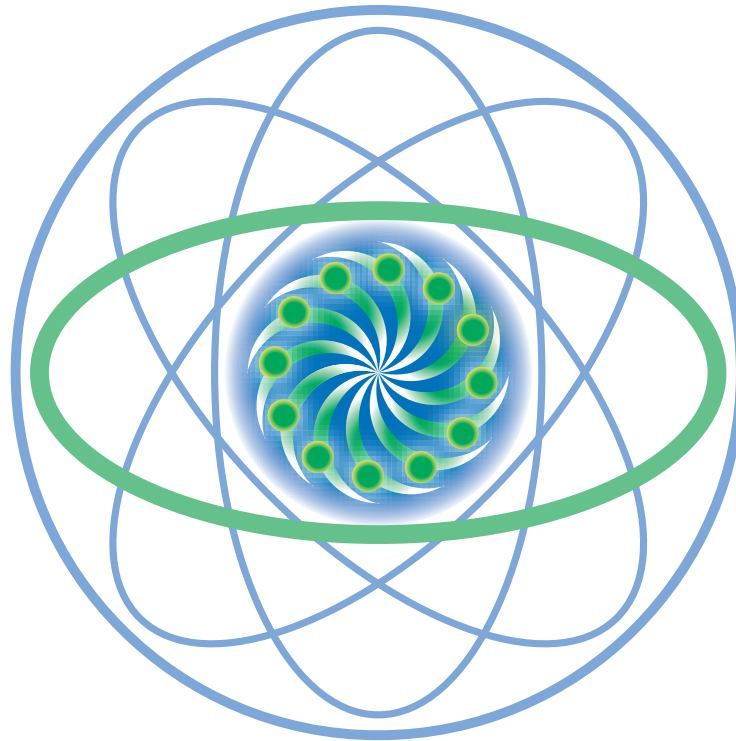
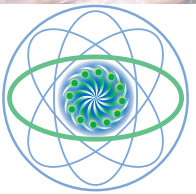


eSubs Selling Ourselves to the World

Colin Andrew Brown, Buchenbach, Germany.
working for Roche Pharmaceuticals, Basel, Switzerland.



St Albans Teich, Basel



Built by St Albans monastery, about 1152.

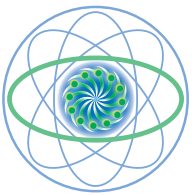
eSubs Selling Ourselves to the World

What is an eSub?

eSub experience.

Future Changes.

Consequences/Thoughts.



What is an eSub?

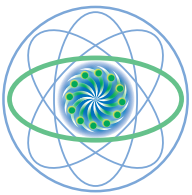
Data package electronically sent to the FDA, a part of Module 5 of an NDA, or to other health authorities:

Reviewers Guide.

Source and analysis datasets in XPT format.

Data Definitions Document (define.pdf), full specifications for all data and derivations, including annotated CRF.

Standalone Programs.



eSub Experience.

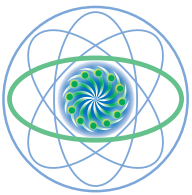
Team Formation/ Process Development.

Initiated a group in India to perform eSub activities.
Joined the Roche eSub group.

Hands on Experience.

Reviewers Guide.

Source and Analysis Datasets in XPT format.



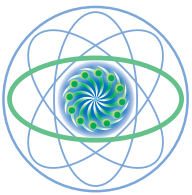
eSub Experience.

Hands on Experience.

Data Definitions Document (define.pdf), full specifications for all data, including annotated CRF.

Interesting!

interesting!

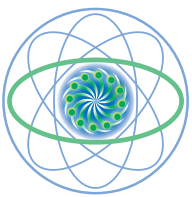


eSub Experience.

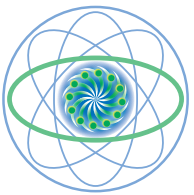
Hands on Experience.

Standalone Programs.

Program Output Type	Lines of code in original Program	# of Macros invoked	Lines of code in Standalone Program
Analysis Dataset	421	3	1292
Analysis Dataset	400	2	1114
Efficacy Output	86	18	18495
Efficacy Output	99	42	22067



Future Changes- Where will they Go?

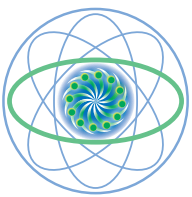


eSub Consequences

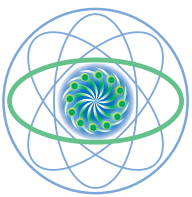
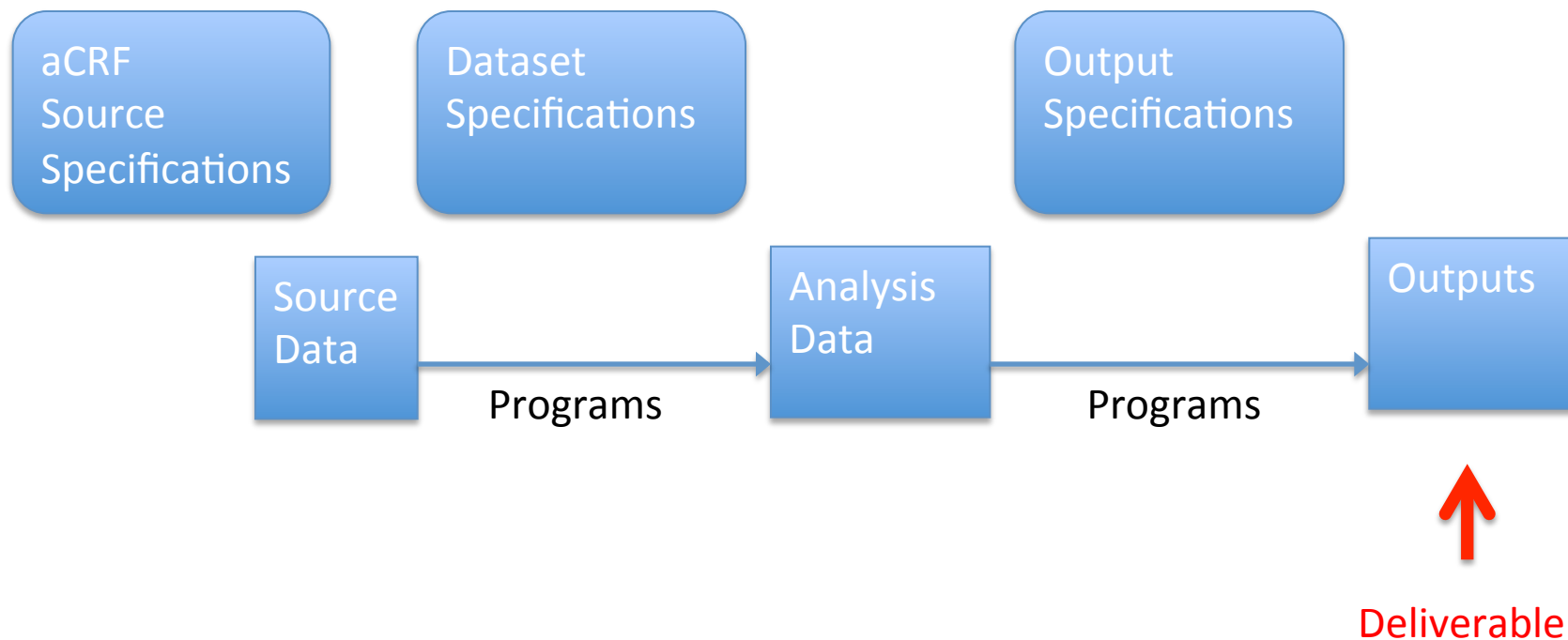
How different will European eSubs will be from FDA eSubs?

Will further authorities demand eSubs?

Will all studies be required to be submitted?

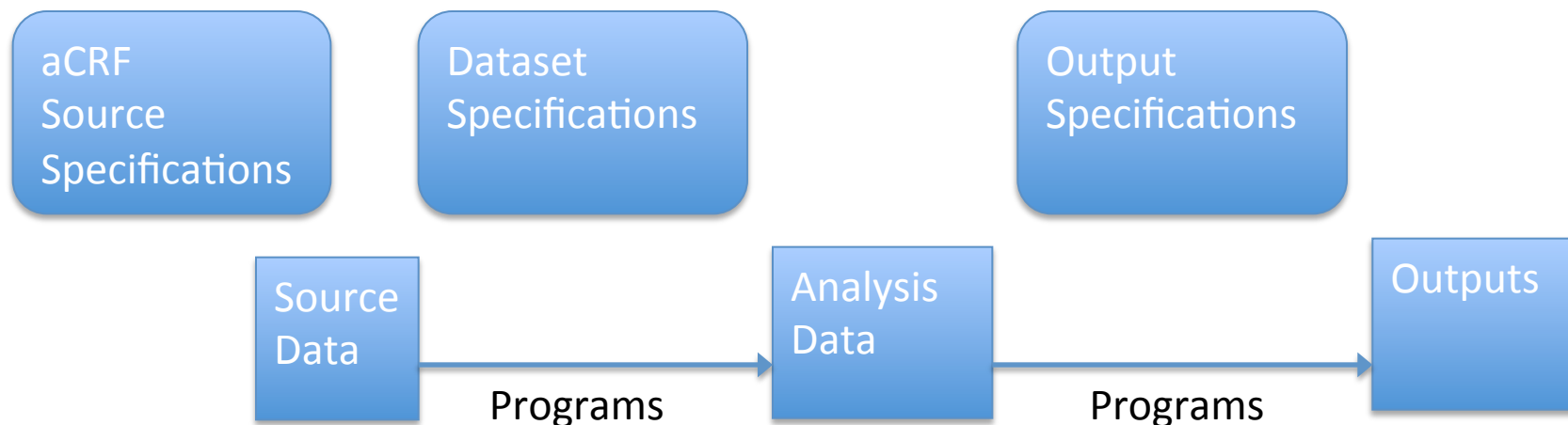


eSub Consequences



eSub Consequences

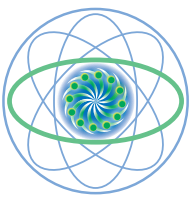
← Everything is a Deliverable →



← Everything is a Deliverable →

aCRF, Specifications, Source data, Analysis data, all are as important as the programs and outputs have been in the past.

... and will every Study will be a Deliverable?

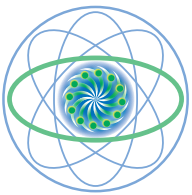


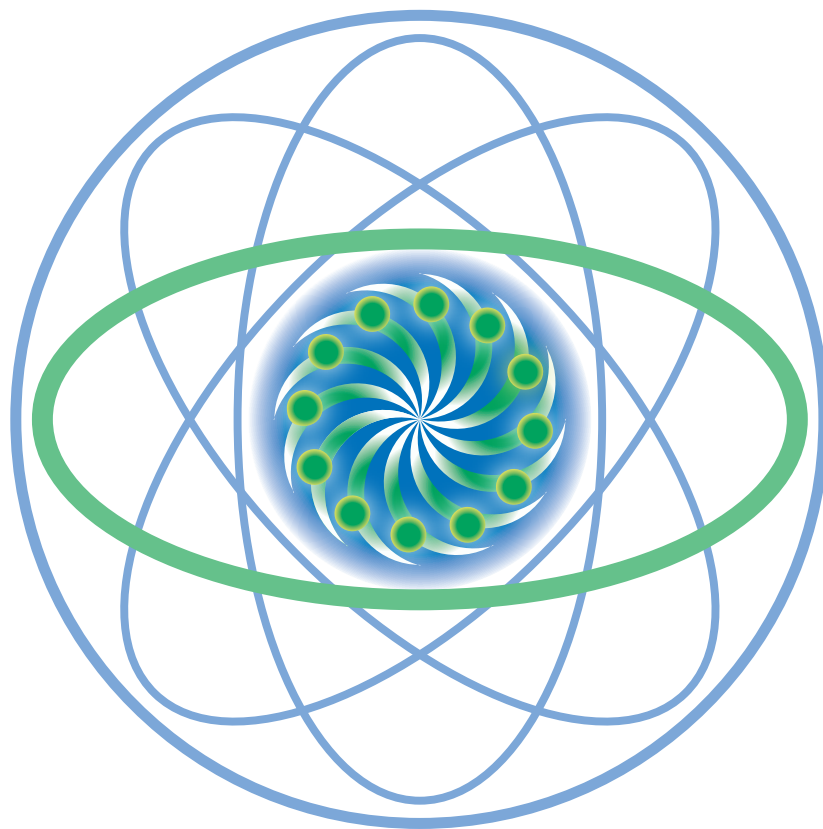
eSub Thoughts

Our work is achieving a higher degree of visibility.

Our datasets and outputs are always correct- but we need easy readability as well as quality in our Specifications.

How we sell our products to the World, is how we sell Ourselves to the World





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