



Statistical End-User Tool Development

October 10, 2017

Mickael Borne

Paper AD04

Edinburgh 2017

Digital Innovation in Healthcare | 8th–11th October

Edinburgh International Conference Centre



How can I, a biostatistician, promote digital innovation in healthcare?

Statistical End-User Tool

Agenda

01

The method of development

02

An example of a statistical end-user tool

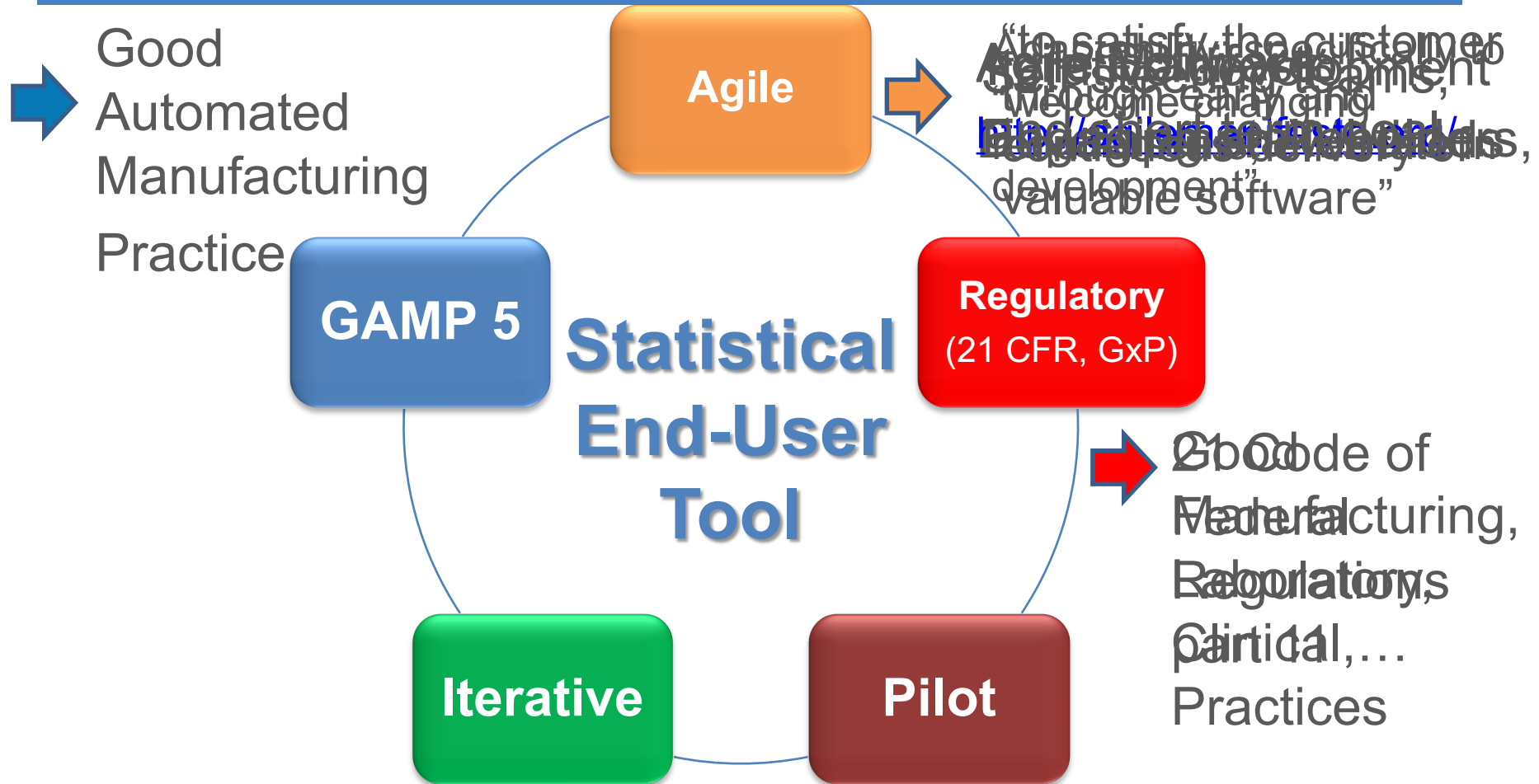
03

From Biostatistician to Developer

A Statistical End-User Tool is:

1. A computerized system
2. Used in regulatory areas (GxP)
3. By a non statistician
4. To create a statistical report

The method of development



The method of development

- Role and Responsibilities

Supplier	Client
Project coordinator	Project leader
Tester	User leader
Experts	IT representative
	Validation leader, QA representative,...

The method of development

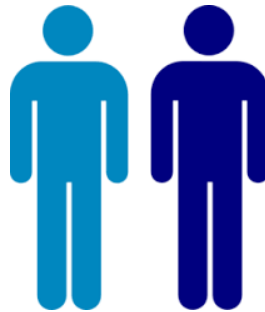
- Main Steps of the Project



The method of development

- Key Figures

2
People



100
FTE



8
Months



80,000
euros

Example

The Request:

- A computerised system to produce a statistical report for method comparison analysis
- Main user requirements:
 - Windows® for OS,
 - Excel to request the report,
 - Word and PDF reports,
 - Use the Bland-Altman plot to assess the agreement

Example

The Offer:

- provide the client with an estimation of the global cost of the project
 - Imagine a solution,
 - Anticipate any potential technical problems,
 - Identify all the deliverables,
 - Estimate the needed FTE

Example



EXCEL

Allow data entry and request for a statistical report

User Interface



SAS

Used in batch mode for statistical computation and reporting

Statistical Core



WORD

Create the statistical report in Word and PDF renditions

Publishing

Example



MethCompDataEntry.xlsm - Excel

FILE

HOME

INSERT

PAGE LAYOUT

FORMULAS

DATA

REVIEW

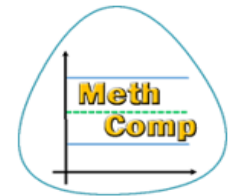
VIEW

DEVELOPER

SAS



Method Comparison



Study	
Description	
Requestor	
Analyte	
User Acceptance Limit	
Method 1 (Reference)	
Method 1 description	
Method 2 (Compared)	
Method 2 description	
Unit	

Sample Id

Method 1

Method 2

Submit

Example

MethCompDataEntry.xlsm - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW DEVELOPER SAS

 **Method Comparison** 

Study	TestXX01
Description	This is the title of the study TestXX01
Requestor	Requestor Name
Analyte	Analyte A
User Acceptance Limit	Not managed
Method 1 (Reference)	Method A
Method 1 description	Description of the method A (reference)
Method 2 (Compared)	Method B
Method 2 description	Description of the method B (new)
Unit	Unit of Analyte A

Sample Id	Method 1	Method 2
Subject_1	5.2	5.2
Subject_2	12.8	7.2
Subject_3	13.2	10
Subject_4	13.6	9.8
Subject_5	12.8	14.8
Subject_6	13.2	15.6
Subject_7	14	15.4
Subject_8	15.2	16.6
Subject_9	15.8	13.4
Subject_10	18.4	16.6
Subject_11	10.0	15.6

Submit

MethComp DataSample (+)

Select destination and press ENTER or choose Paste

AVERAGE: 24.49

Example

Report_2017-0005_30AUG2017.pdf - Adobe Acrobat Pro

File Edit View Window Help

Create ▾

1 / 10 100%

Tools Comment Share

 **Method Comparison** 

Statistical Report – Method Comparison

TestxxXXxx

Description: This is a test

Analyte:	Analyte A
Unit:	MyUnit
Requestor:	Me as Requestor
Method A:	This is the description of Method A
Method B:	This is the description of Method A

Requested by:

From Biostatistician to Developer

- Why choose a CRO to develop a computerised system?
 - A better understanding of the need
 - CRO statisticians are trained to be agile, responsive and flexible
- Why CROs offer development services?
 - Engage in a long-term relationship with the client
 - Enriched in current skills like GAMP 5 knowledge
 - Provide new attractive career path
- Why a statistician might like to become a developer?
 - Not always a conscious act
 - Diversion from the day-to-day work
 - To meet new people, discover user objectives

Conclusion

CS that allows a non-statistician to create a statistical report

Composed of a UI, a statistical core, and a publishing unit

Regulatory requirements

→ 21 CFR, GxP

Agile manifesto and GAMP 5 principles

Feel free to install the tool provided in the appendix of my paper

One more thing...

Individuals and Interactions
Sustainable
Simplicity
Be Agile Design Versioning
Responding to Change
Think Maintenance
Externalization
Short Program
Communication
Test Motivated SAS
Qualify Validation GAMP
Face-to-face
Self-organizing
Customer Collaboration
Working Software
Multi-languages

Questions?



CONTACT INFORMATION

Mickael Borne

Work Phone: +33 1 84 19 35 59

Email: mborne@4clinics.com