

ClinXPORT

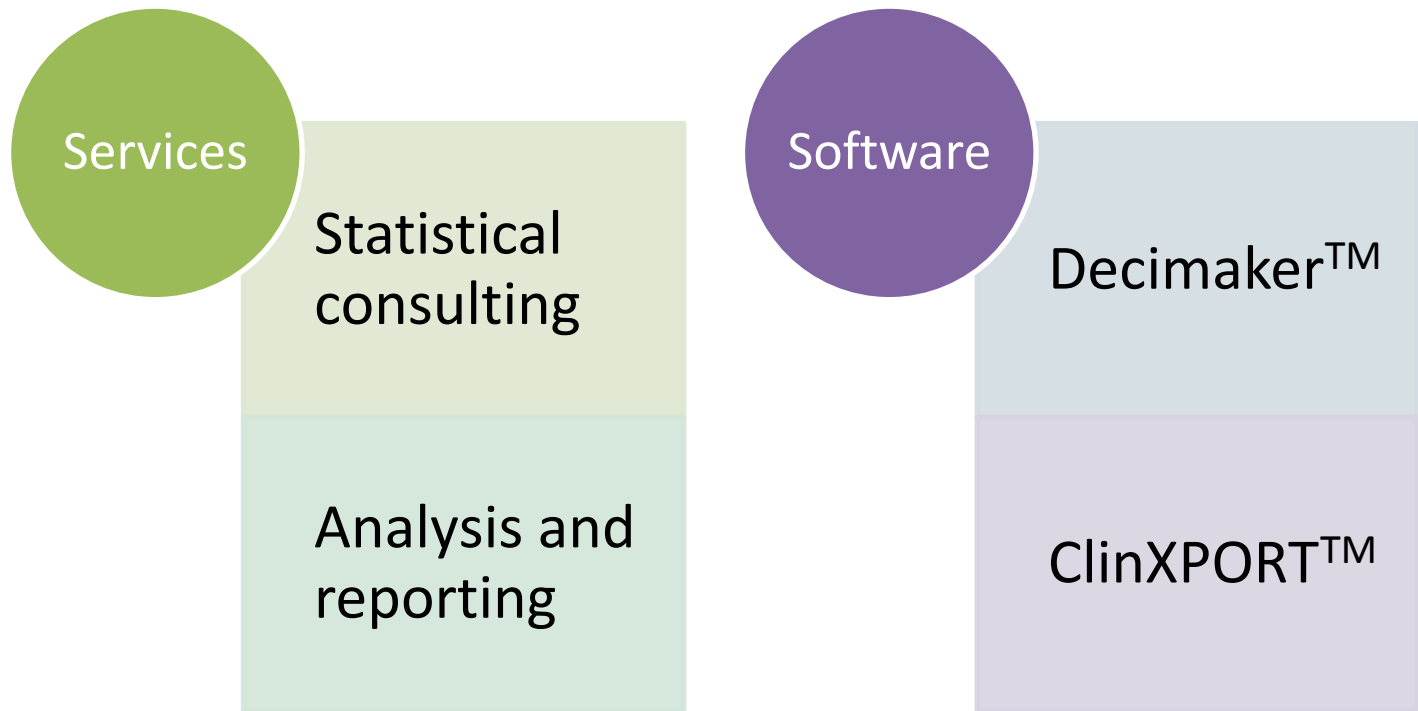
Efficient reporting solution by ClinBAY

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Presentation of ClinBAY

- ✕ ClinBAY is a **statistical CRO** specialized in clinical trial design and analysis
- ✕ Provide innovative **statistical** solutions to decision makers



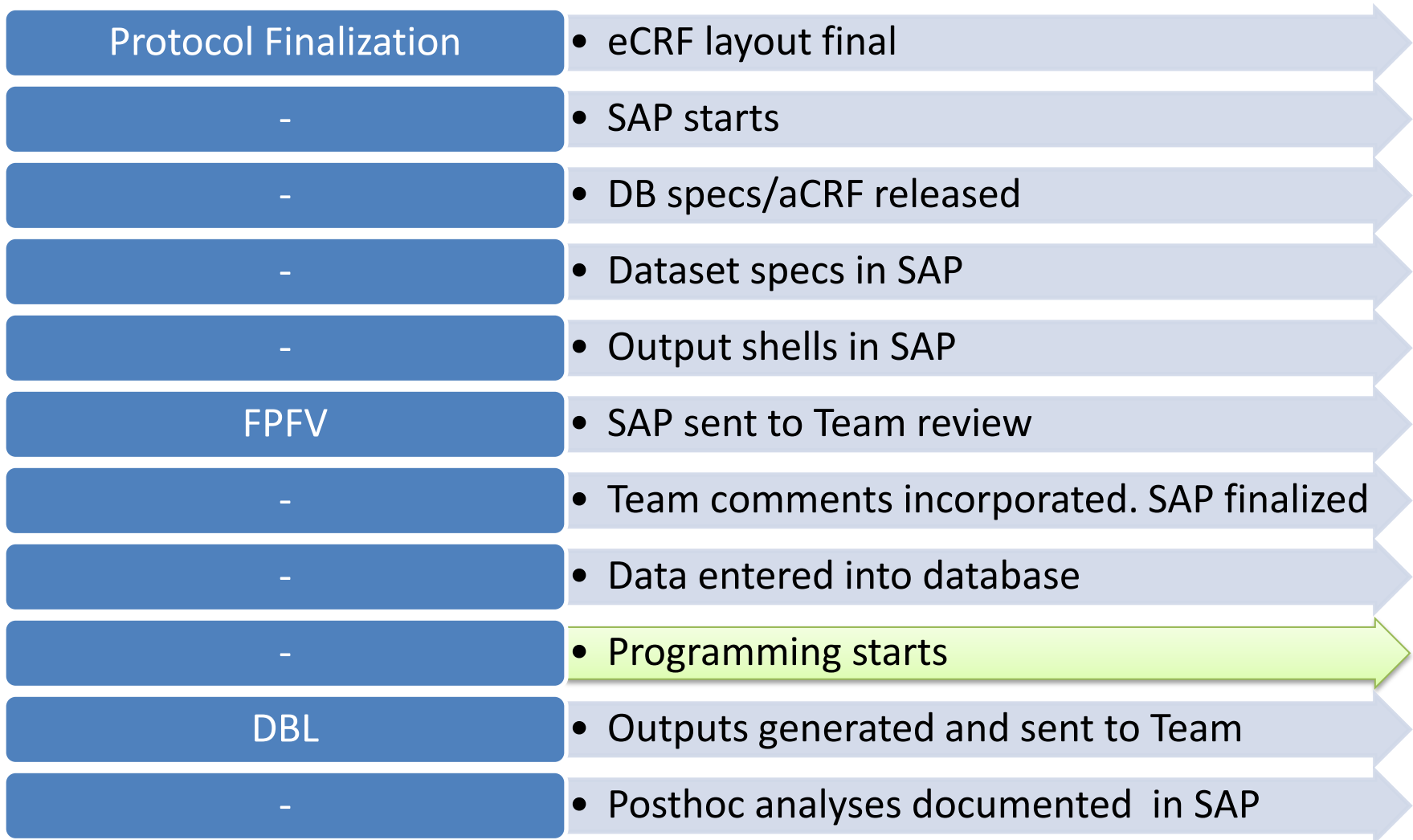
Outline

- 1 What is **CLINXPORT** ?
- 2 Objectives
- 3 How does it work?
- 4 Facts and figures
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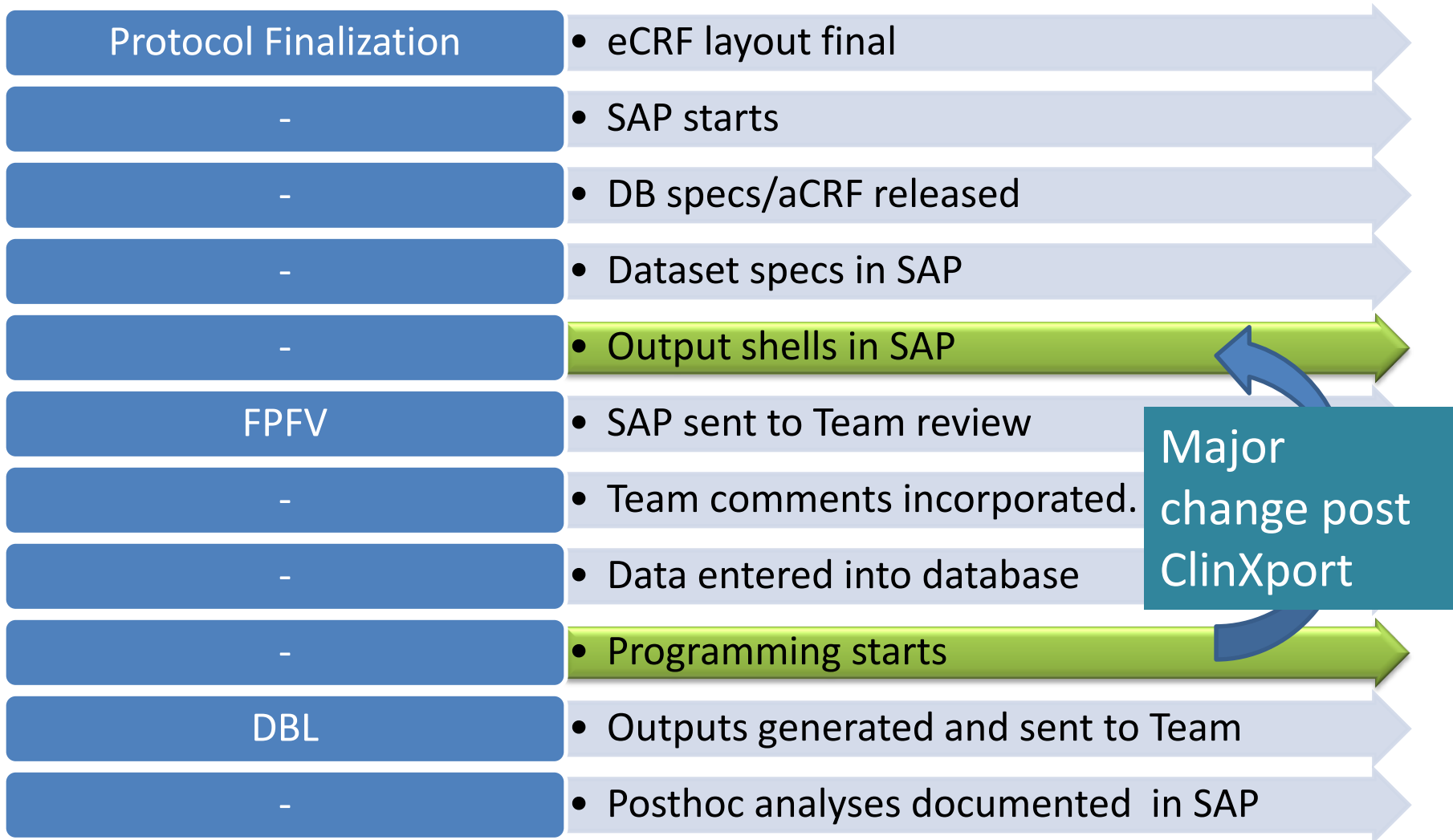
What is ClinXPORT?

- ✕ **CLINXPORT** is a reporting solution to automate the production of **tables, figures and listings (TFLs)** from SAP requirements
- ✕ Firstly developed as an **internal reporting tool** for clinical trials, then in **collaboration** with a pharmaceutical customer
- ✕ Licensed software released by ClinBAY

Scenario today



Scenario today



Objectives

- 1 **Productive**: about 25% time saved compared to standard SAS reporting methodology (increased with the use)
- 2 **Reusable**: Modularized programs can be reused between studies with no or only few changes
- 3 **Flexible**: able to handle various customer requirements, fully customizable
- 4 **Easy-to-use**: Familiar, user-friendly interface
- 5 **Automated**: PROC REPORT and other common SAS statement entirely automated
- 6 **Professional**: Clear process defined, validated and supported product

Architecture of ClinXPORT

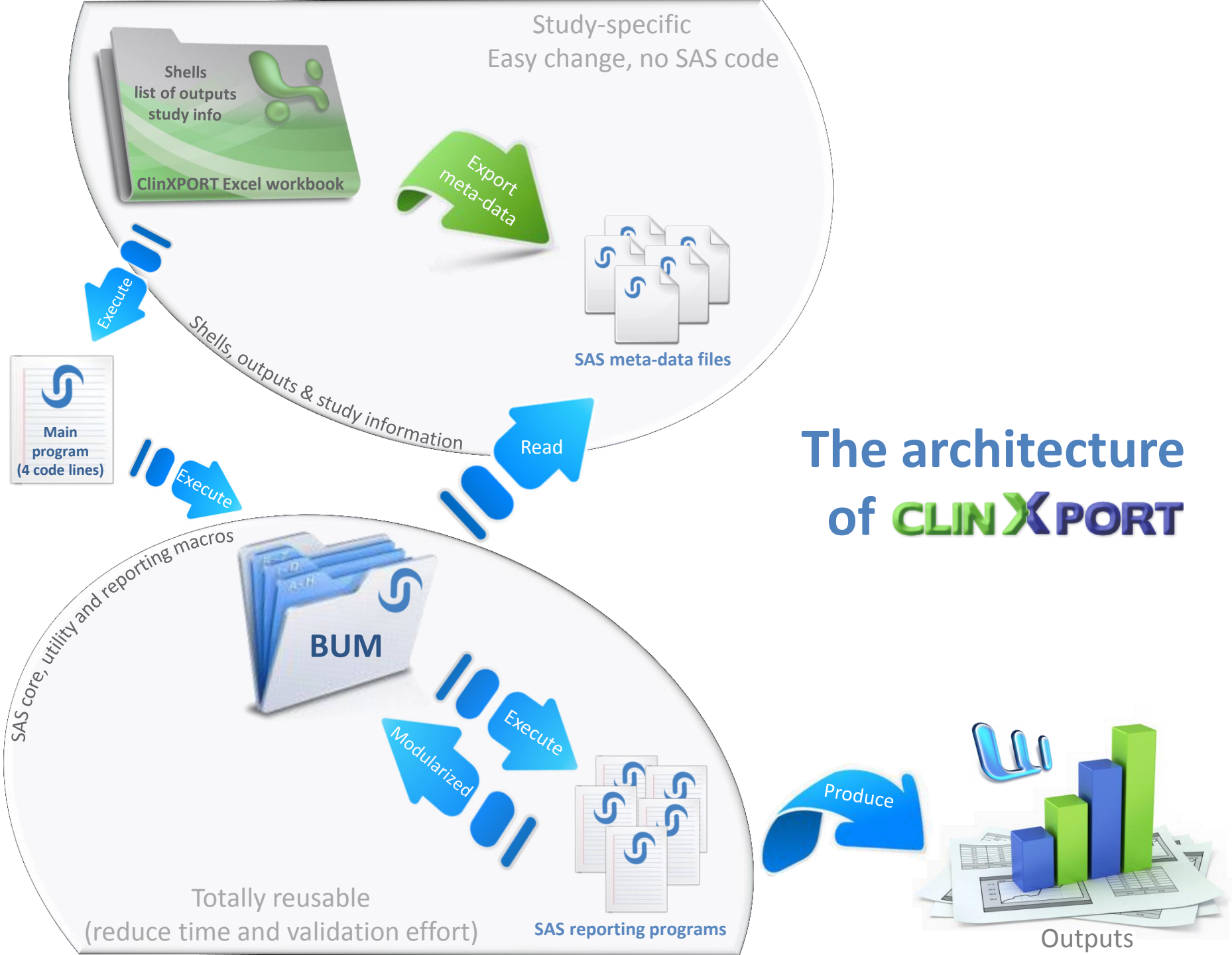
ClinXPORT has 2 components:



A **Microsoft Excel** interface to define the table of content and shells for the TFLs (**specification step**)

A **SAS** macro library (BUM) to generate TFLs (**reporting step**)





A quick tour of ClinXPORT:



A quick tour of ClinXPORT - Summary

- Specification step:
 - First, TFLs requirements are defined in a excel workbook as part of the SAP
 - Output shells document is generated automatically for clinical team review
- Reporting step:
 - Reporting information is tagged as meta-data in Excel and exported to SAS
 - SAS code is generated automatically from within ClinXPORT
 - Outputs & logs can be opened from ClinXPORT

Change management is EASY!

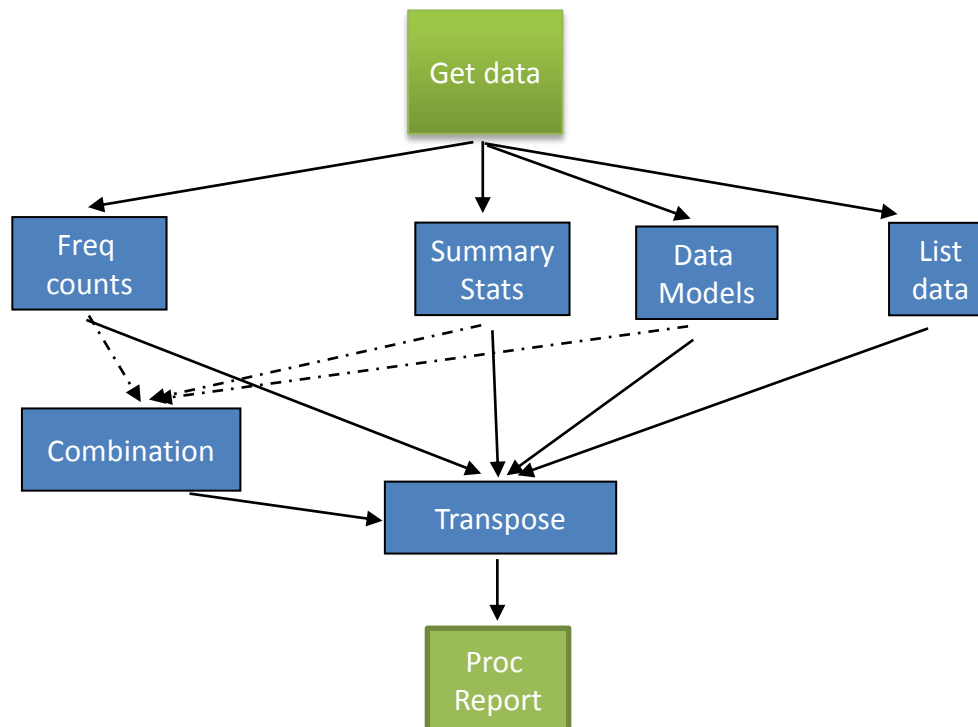
What happens if one wants to modify a report?



- Changes are managed from the Excel console
- Perfect matching between requirements and outputs is maintained
- Project hand-over is easy!

Modular SAS programs

- Simple reports can be **created directly from ClinXPORT in Excel** without any additional SAS programs
- For more complex reports, **modular SAS programs** can be assembled easily from the ClinXPORT SAS library.



Modular SAS programs - Example

- Flagging abnormal ECG data
- No need to manage **Get data** and **Proc Report** at all!

```
%macro p_ECGList2(data,subset=%str(1));  
* reset ADS dataset;  
%rsetdset(names=ads ads2, lib=work);  
  
* create ADS dataset by subsetting from &data using metadata definitions;  
%rep_subset(in=&data, out=ads, subset=&subset);  
  
* flags out of range QT values;  
data ads2;  
    set ads;  
    if QTUOUT >. then  
        QT_=trim(put(QTIUNC1N,6.0))||repeat('+',QTUOUT-1);  
    else QT_=trim(put(QTIUNC1N,6.0));  
run;  
  
%* Sort data before report;  
proc sort data=ads2 nodupkey;  
    by TGP1A CS FROMDAY ECG1T ;  
run;  
  
* Execution of proc report statement;  
%rep_list(ads2,autosort=0);  
  
%mend p_ECGList2;
```

And much more...

- **Additional features** are available to assist in the reporting workflow:
 - Output file format selection (rtf, txt, html, pdf), page setup and style
 - Sheet locking/unlocking
 - Automated comparison of report versions
 - Validation documentation for SAS programs
- **Integration** within customer environment:
 - Windows/Unix compatibility
 - Integration into document management systems, SDD,...

Summary of basic principles

- ① All information about shells, programs, data, and TFL are defined in an **Excel file at SAP stage**
- ② Metadata is passed to SAS for **automated production of simple TFLs**
- ③ Ad-hoc programs remain **simple** thanks to library of **modular SAS macros**.
- ④ Reporting managed from within ClinXPORT environment.
- ⑤ Changes to TFLs, copy/pasting, data subsetting is **easy to do in Excel without further SAS code**.

Facts and Figures

- ❑ **CLINBAY** uses ClinXPORT for reporting since 2009. Shell library defined for >**10** different customers.
- ❑ **30%** gain in **productivity**, without discounting software development effort.
- ❑ ClinXPORT for **Office 2007/2010** offers more than **20** functionalities, including RTF documents comparison, validation report generation, etc
- ❑ The SAS BUM package includes **73** macros that can be used and extended to facilitate and automate reporting
- ❑ Version 1.4 is fully validated (IQ/OQ/PQ)

Product information

- Fully supported product:
 - Yearly licenses for Excel add-in + BUM
 - 7/7 support, maintenance and upgrades
- Validation package available for installation qualification.
- Custom developments possible (Excel and SAS) for software integration
- Easy-to-Learn Training program is provided
- Discounts offered for CT services

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Thank you
For your attention!