



Timeline Shift

**Vijaya kumar
Radhakrishnan**

Team Lead



Trust the **M****A****G****I****C** of
New Beginnings

This is an unusual paragraph. I'm curious how quickly you can find out what is so unusual about it? It looks so plain you would think nothing was wrong with it! In fact, nothing is wrong with it! It is unusual though. Study it, and think about it, but you still may not find anything odd. But if you work at it a bit, you might find out! Try to do so without any coaching!

Agenda

- **Introduction**
- **Timeline Issue**
- **Data Sharing**
- **Data Analysis**
- **Reporting**
- **Projected vs Actual**
- **Submission**
- **Conclusion**

Introduction

Time and Cost of drug development has risen markedly in the past 30 years

Reporting values exceeding in millions

Spiraling time and costs threaten to make the development of new drugs

Unaffordable for both developing companies and consumers

Efforts should be made to address this problem

All aspects of the drug discovery and development process should be examined for potential cost savings

I focus here in particular on the current reporting activities

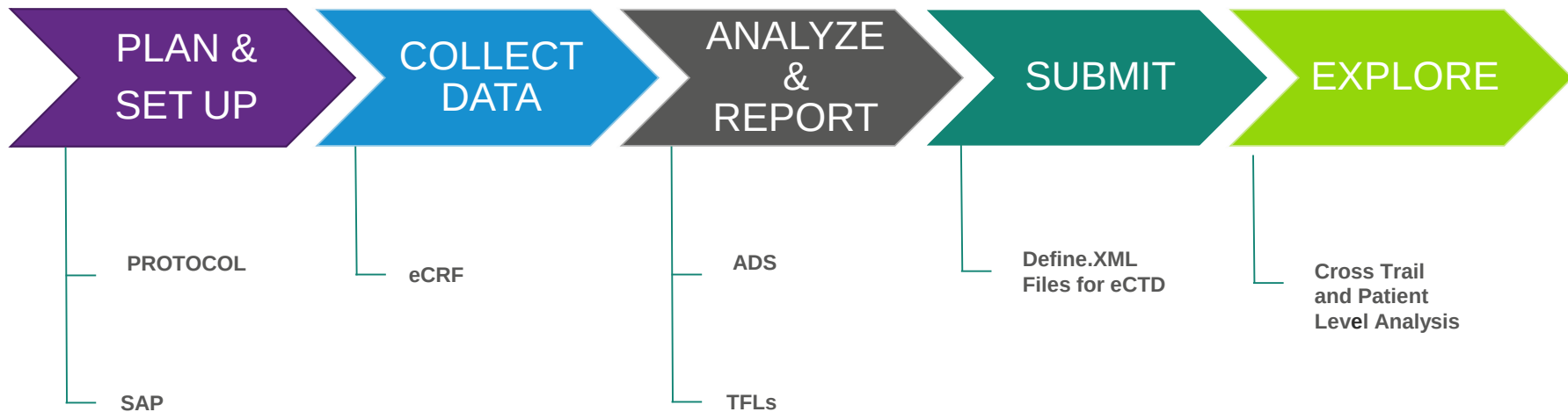
Timeline Issue

The size and structure of a project timeline naturally depends on the project it is describing. A project timeline can be highly detailed, with hundreds of tasks and subtasks, or very simple, listing only a few deliverables and deadlines.

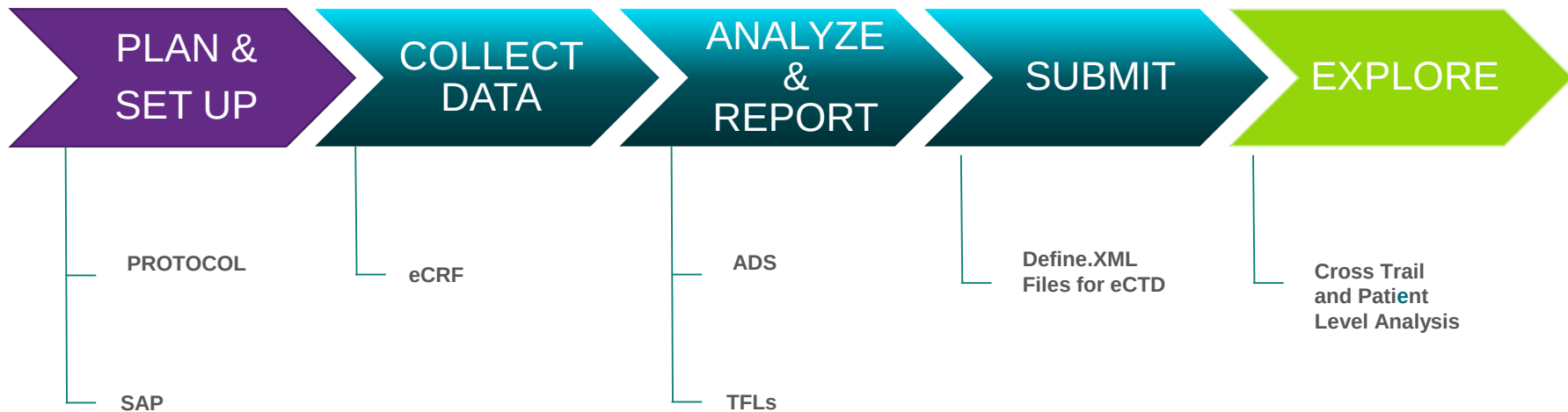
Regardless of how it is constructed, a project timeline needs to capture the following key pieces of information:

- The list of tasks to be completed
- The dates on which the tasks need to be complete
- The expected duration of each task
- Dependencies between tasks

Process



Process



DATA Sharing

- Determining evidence-based medicine and evidence-based public health policies.
- Sharing data from clinical research - Scientific, Economic and Ethical grounds.
- More easily aggregate data for meta-analysis.
- Allows conclusions - re-examined and verified, corrected.
- Also way to new hypotheses to be tested.
- Increases data validity.
- Squeezes more value from the original research investment.
- Helps to avoid unnecessary repetition of studies.



DATA Analysis

- Four Basic Steps of DATA Analysis
- Raw Data Management – Data Cleaning
- Data Reduction I, II – Chunking, Coding
- Data Interpretation – Coding, Clustering
- Data Representation – Telling the Story – Making sense of the data for others

Reporting

Configuration: Table templates containing machine readable formats

- Disposition, Demography, Analysis Sets, Enrolment
- Occurrence (CM, AE, MH)
- Labs
- Vitals
- ECG
- Other

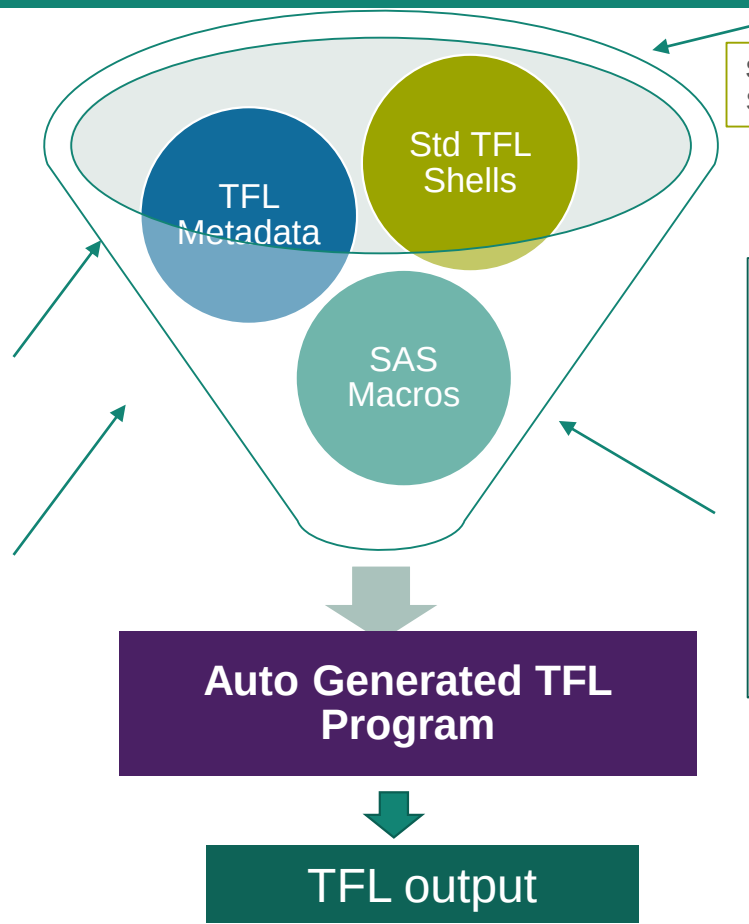
Code- Generation: Reads TFL Meta and calls appropriate macros using meta data to build a TFL Program

Specification: Standard Layouts & Sponsor Specific Layouts

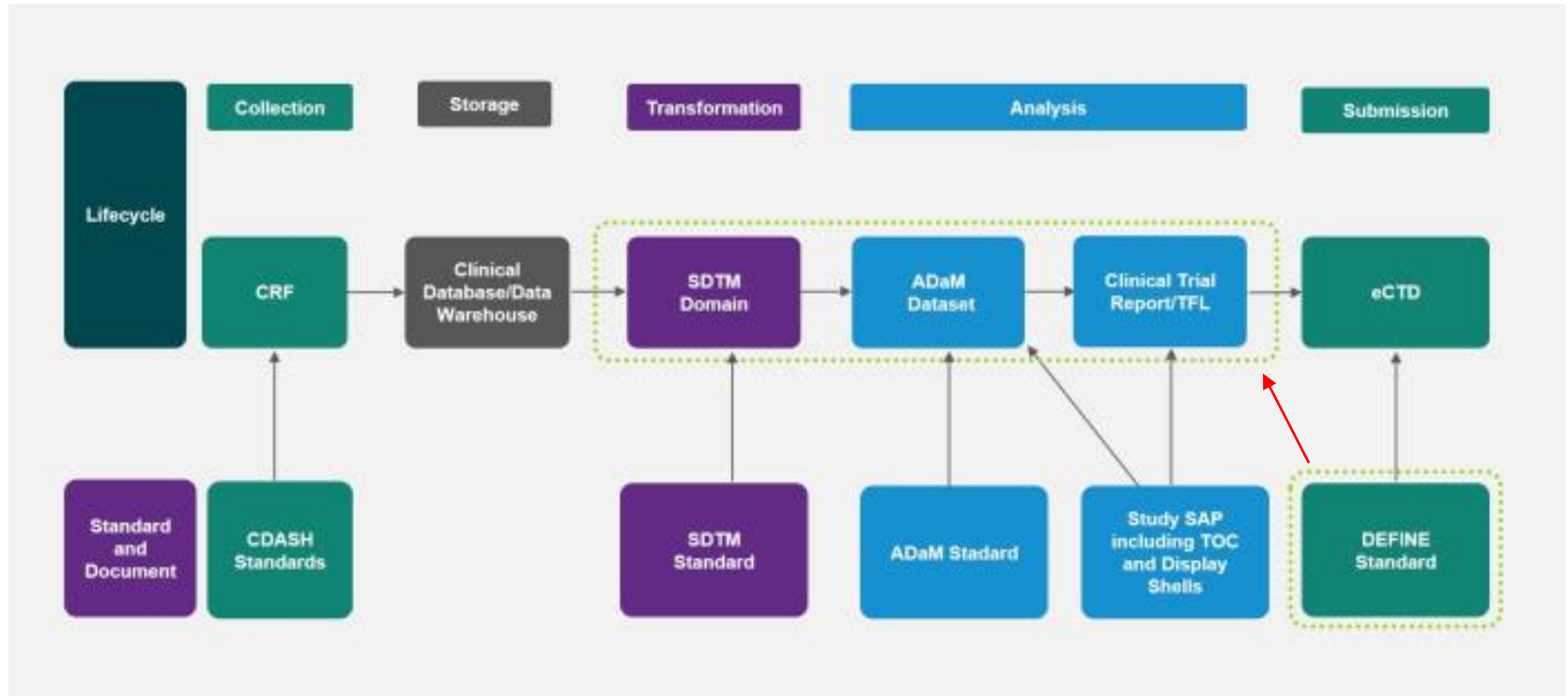
Reporting: Validated SAS Building block macros

- Initialization
- Treatment Columns & Population Counts
- Fetch data from ADaM
- Summary Statistics
- Frequency Counts
- Table Dataset
- Reporting

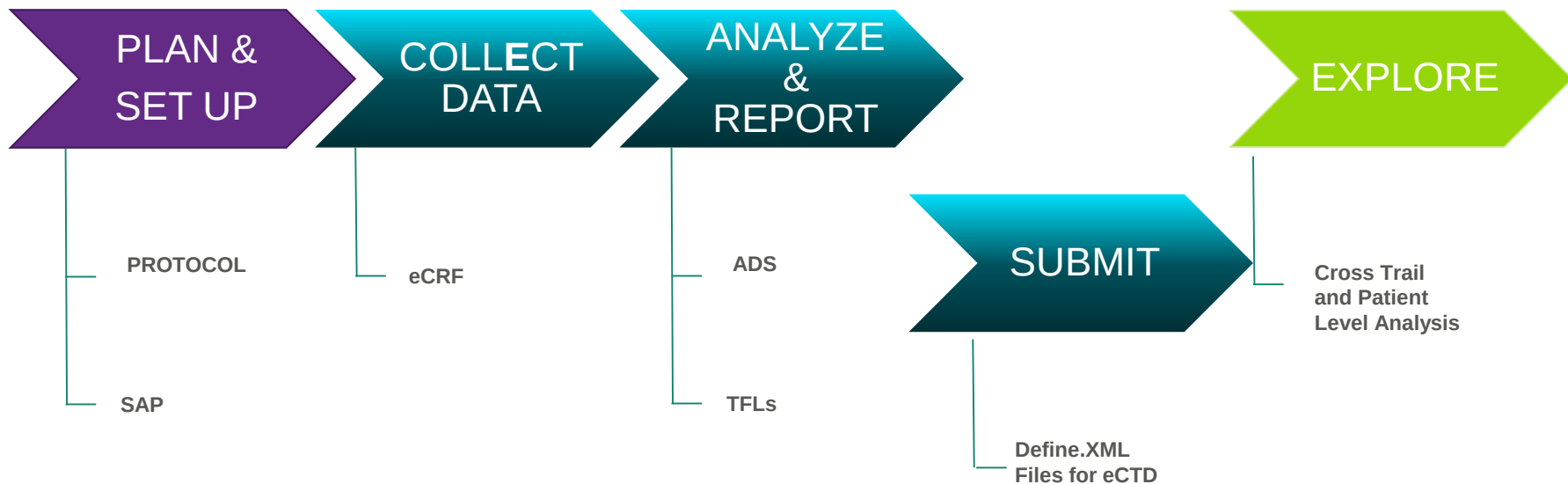
SAS Data Sets



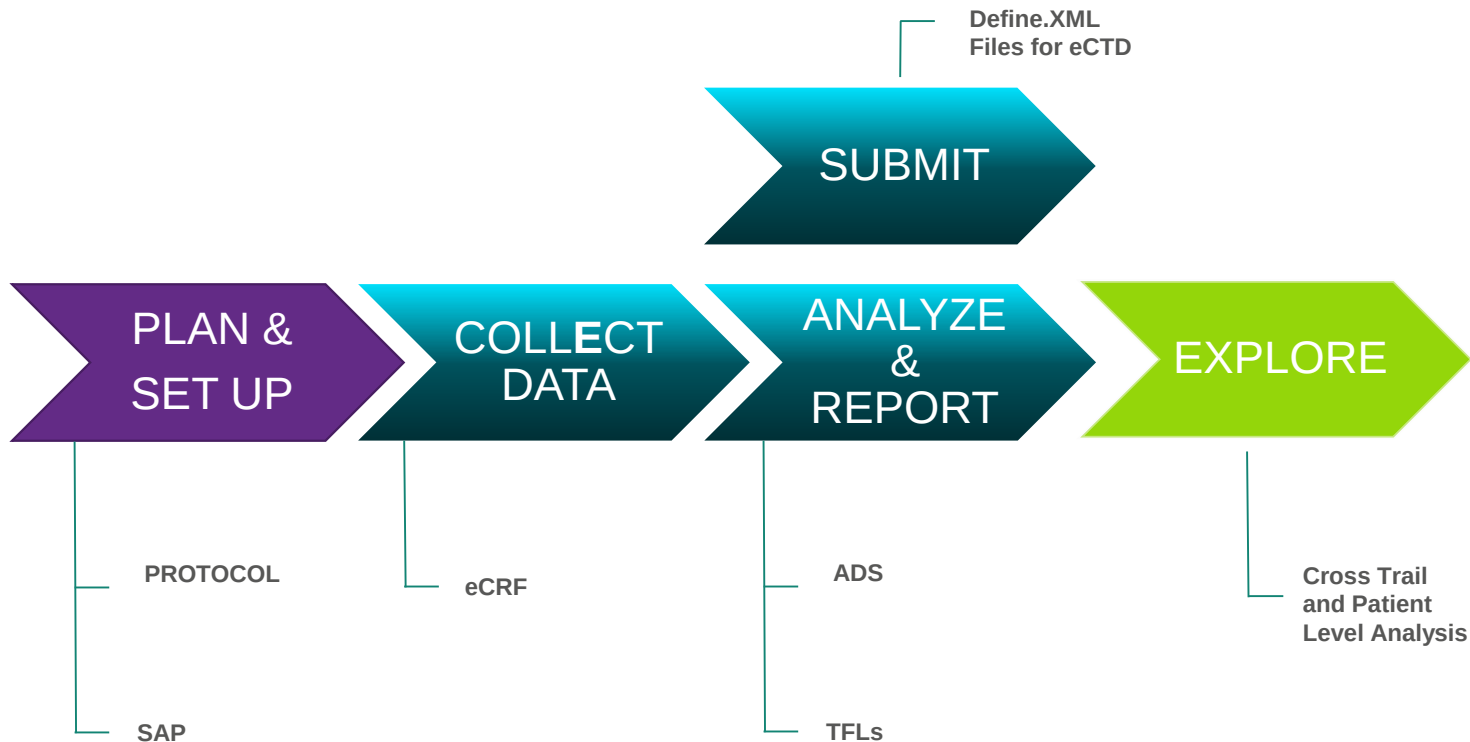
Planned vs Actual



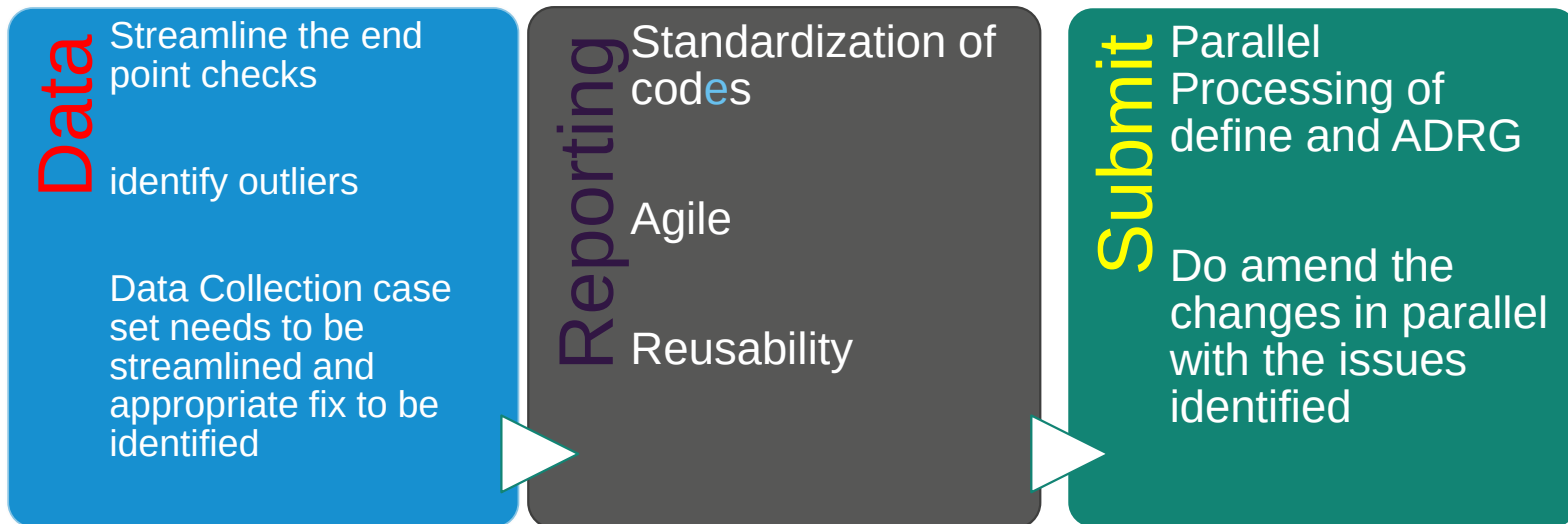
Process



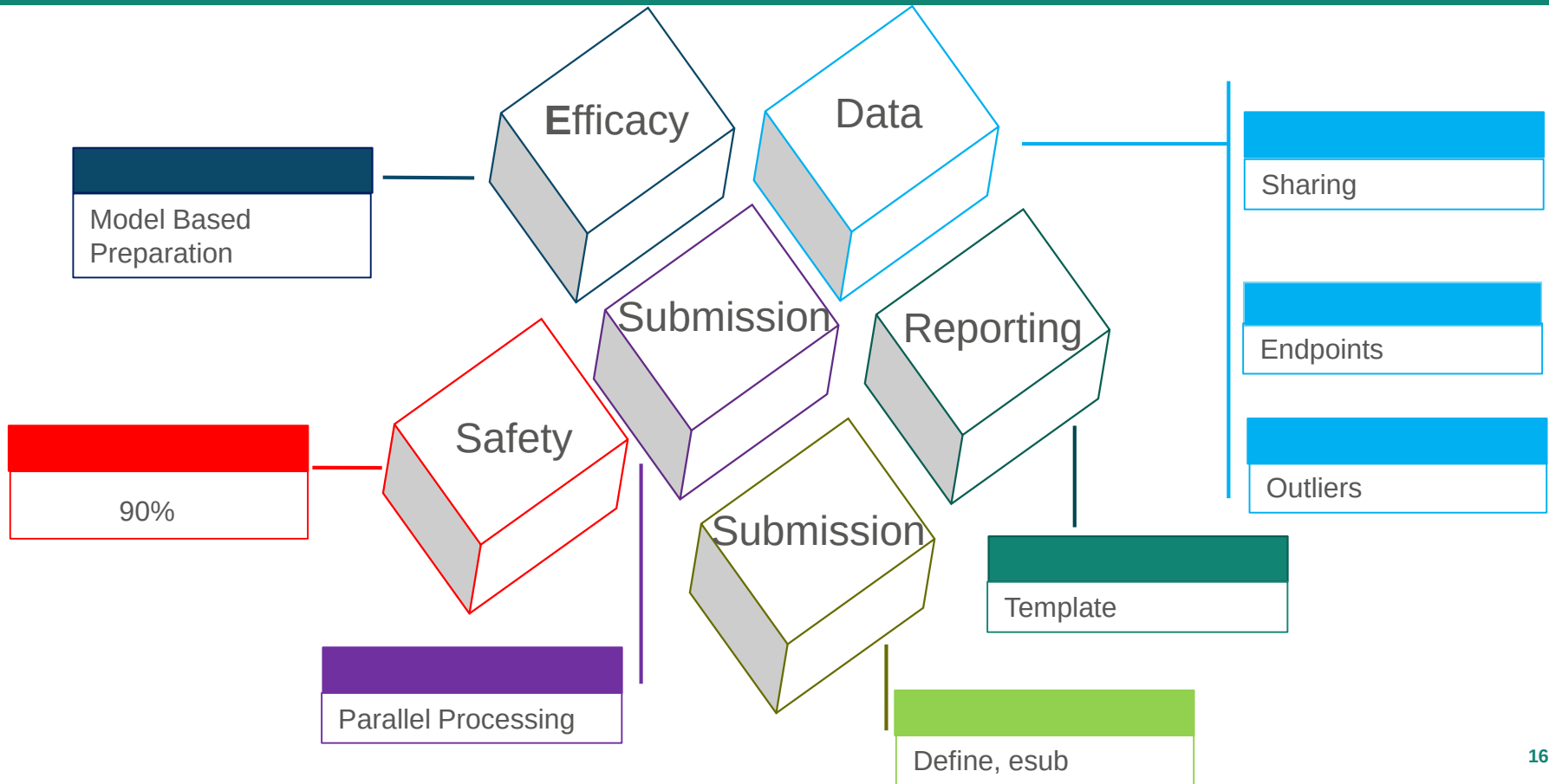
Parallel Process



Approach



Conclusion



Thank you

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