



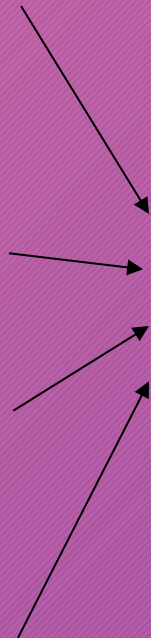
Planning for Data Reporting Processes for Submission- Key Considerations

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Independent Consultant, USA

Annual Conference- PhUSE 2016
Regulatory Stream- RG02

Regulatory Submission- Data Component

Clinical Trial Data



Data Analysis,
Tabulation,
And Reporting



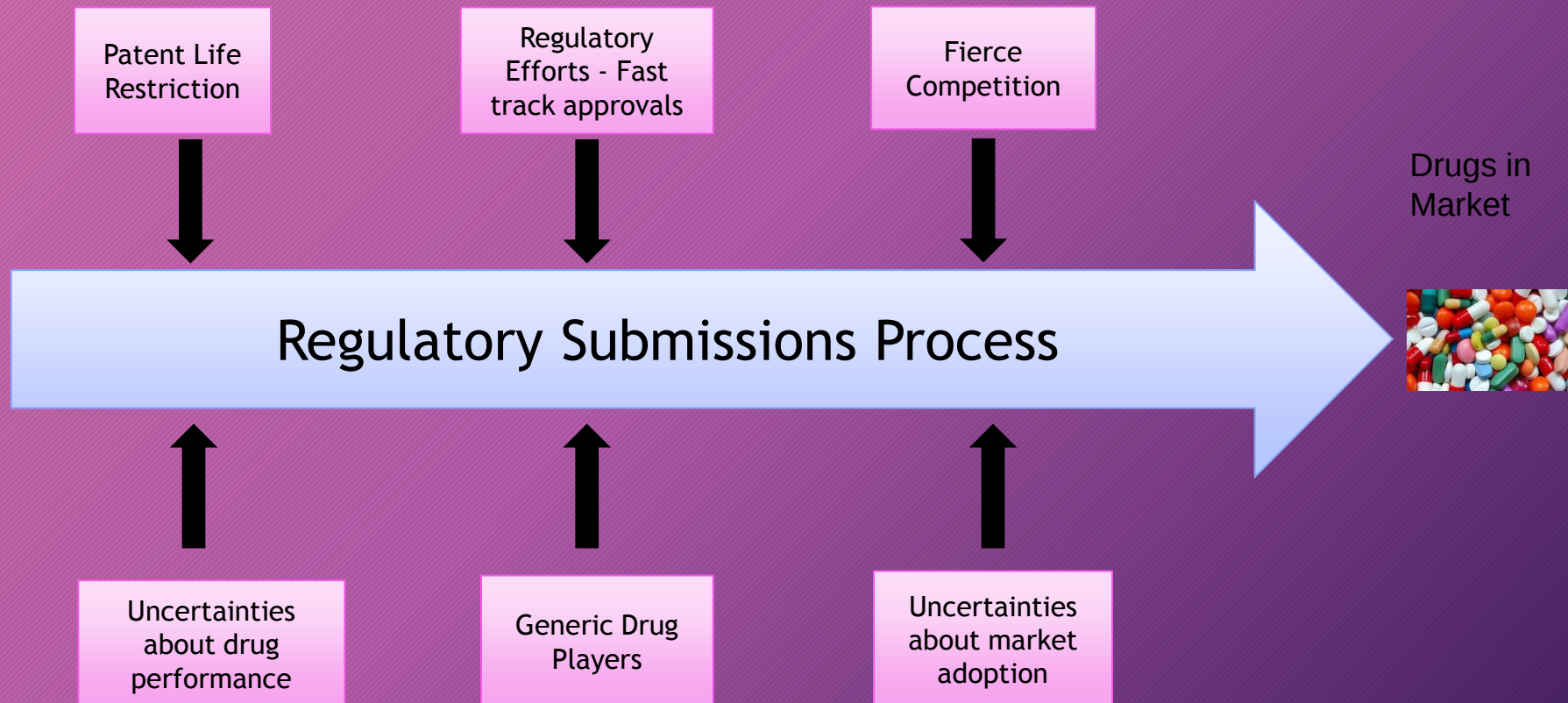
Regulatory Submission

Necessary and
sufficient evidence of
drug safety, efficacy,
and pharmacovigilance

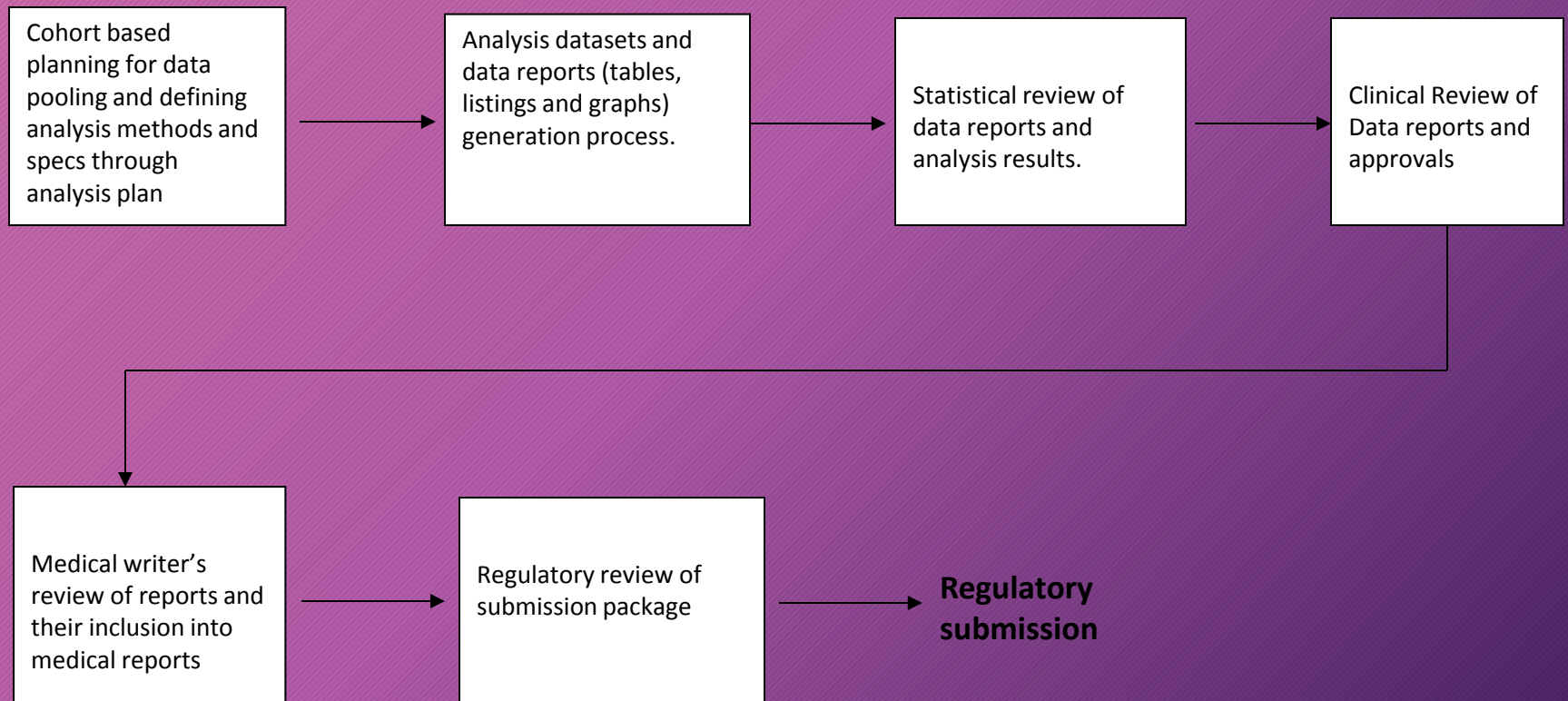


Drug Approval

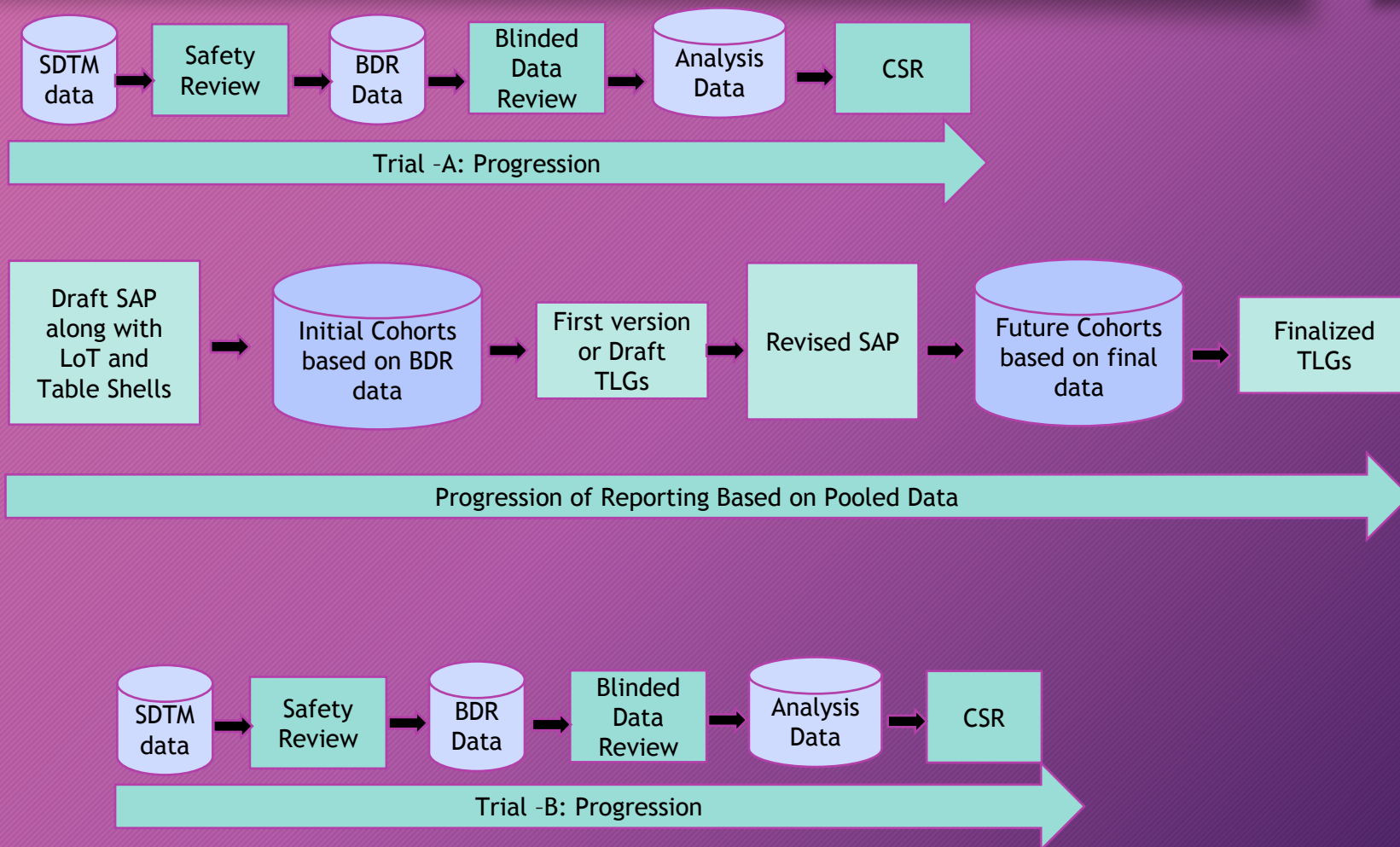
Regulatory Submission- Factors Causing Pressure



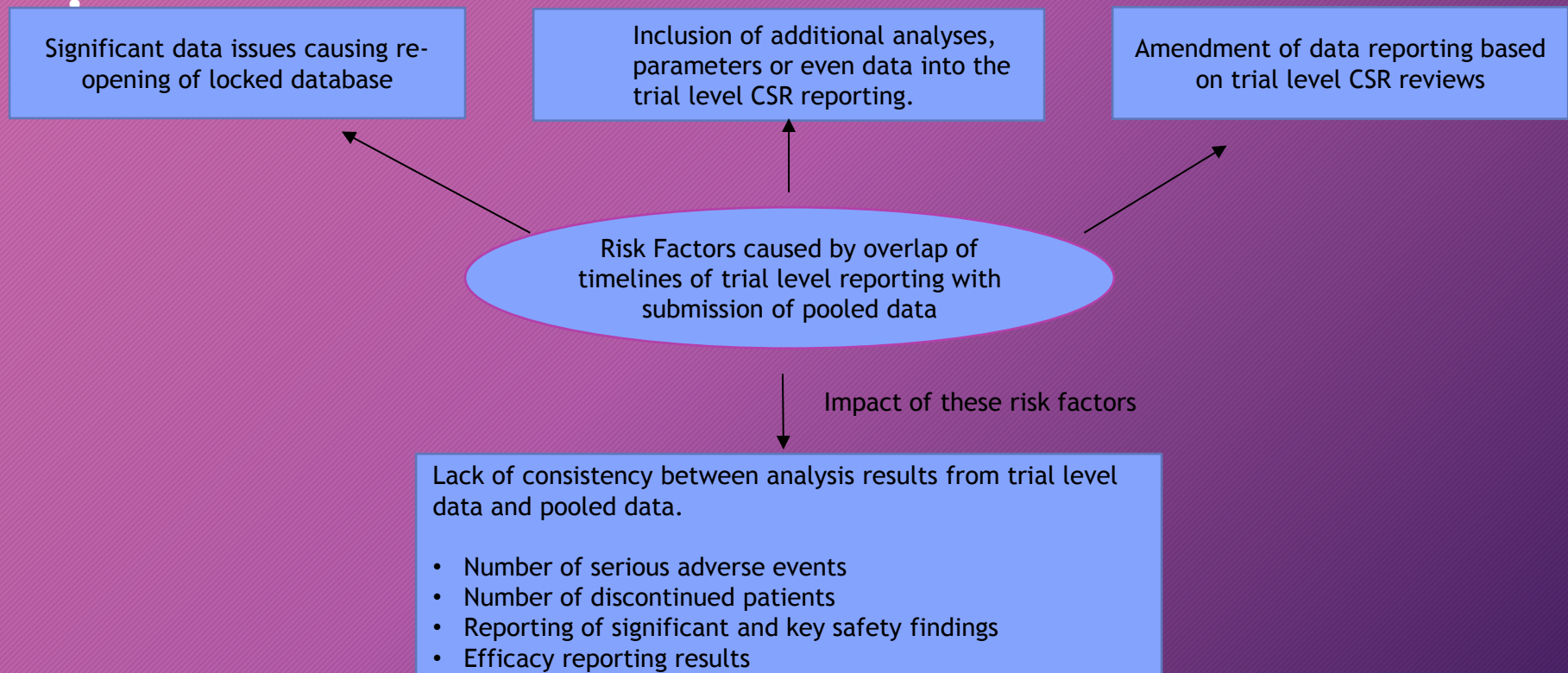
Regulatory Submission - Data Reporting Process



Regulatory Submission- Data Reporting Complexities: Overlap of Timelines



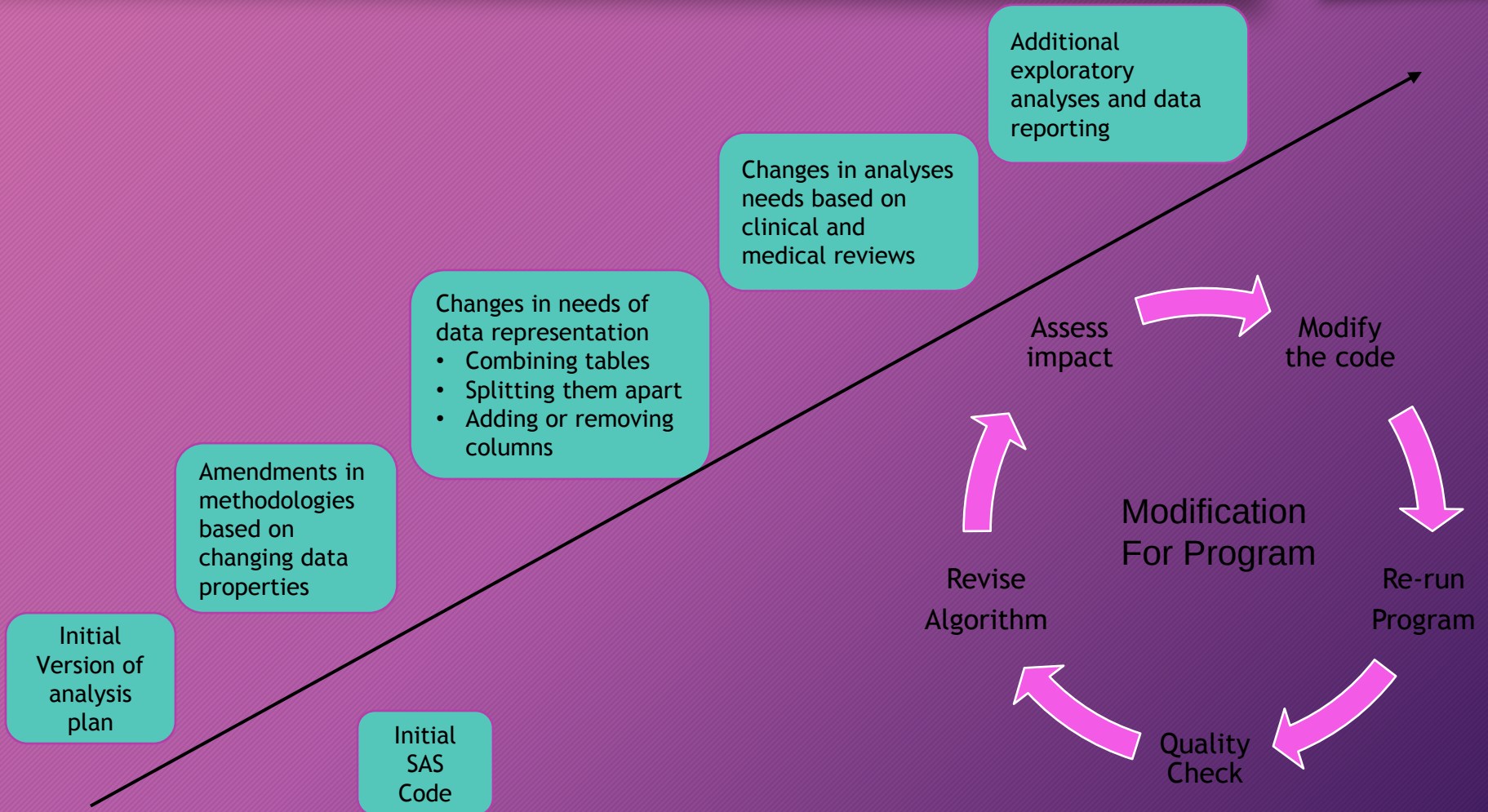
Regulatory Submission- Data Reporting Complexities: Overlap of Timelines



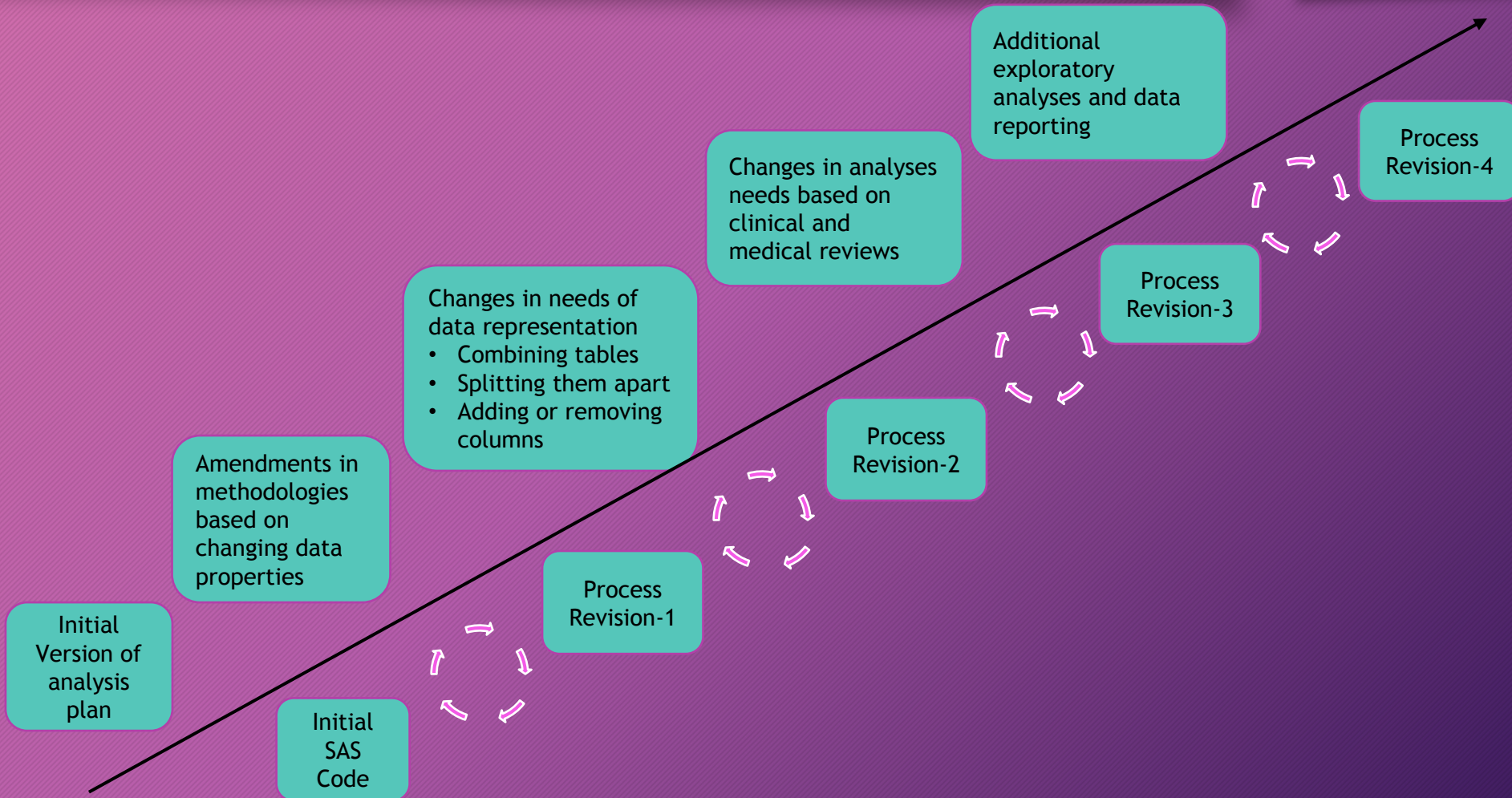
Regulatory Submission- Data Reporting Complexities- Data Standards Differences



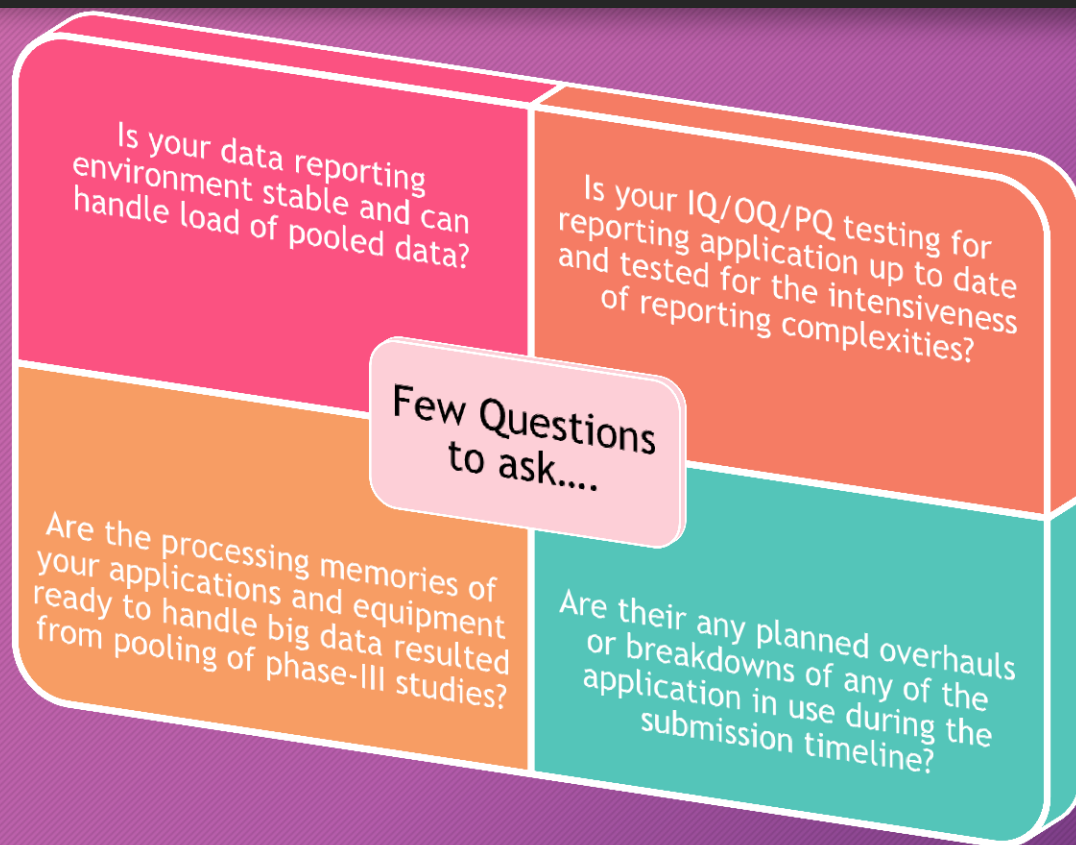
Regulatory Submission- Data Reporting Complexities- Iterative Nature of Data Analysis



Regulatory Submission- Data Reporting Complexities- Iterative Nature of Data Analysis



Regulatory Submission- Data Reporting: Technological Factors



If you don't assess these factors in advance, don't blame the technology.

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blame yourself!!!!

·
·

if you can!

Regulatory Submission- Data Reporting: Human Resource Factors



Continued availability of individuals with strong knowledge of data and analysis methodologies used for the data analysis and reporting of a drug

Regulatory Submission- Data Reporting: Other Reporting Aspects

Submission Timeline

Reporting of
PK/PD and
Biomarker Data

Outcomes
Research
Assessments (in
case of sNDA)

Planning for
Advisory
Committee
meeting

Reporting of
other data not
part of database



Different Submission Types

Food and Drug
Administration

Pharmaceutical
and Medical
Devices Agency

- Drug approved by one regulatory authority and submitted to another one.
- Drug approved for one indication and submitted for another indication for approval from same regulatory authority
- Biologic product vs new drug application
- Co-licensed drug application

European
Medicines
Agency

Country Specific
Regulatory
Agencies

Conclusion

- Effective submission execution should have necessary elements of:

Cante
(Well defined roles and responsibilities)

Toque
(Fit to position of Resources)

Baile
(Effective Execution)



Jaleo
(Quality assessment And Compliance)

Palmas
(Effective timeline Planning)

Pitos
(Necessary Agility in Processes)

Well.....there is always room for some Tapas (improvement)!

Acknowledgement

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Questions?