



PhUSE SDE 2019: Chennai

# *“A stitch in time saves nine” – Programming perspective*



**Jayapandian N**  
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**Theme:** Faster access to new Medicine – cutting down the development life cycle by 25%: Is that a dream or a reality?





# Agenda

// Introduction

// **Case-Studies:**

// Why so many Interim Analysis

// Challenge Status quo

// Collaborative effort b/w DM & Programming

// Terminated Clinical trials

// Potential Options

// Conclusions



# DISCLAIMER

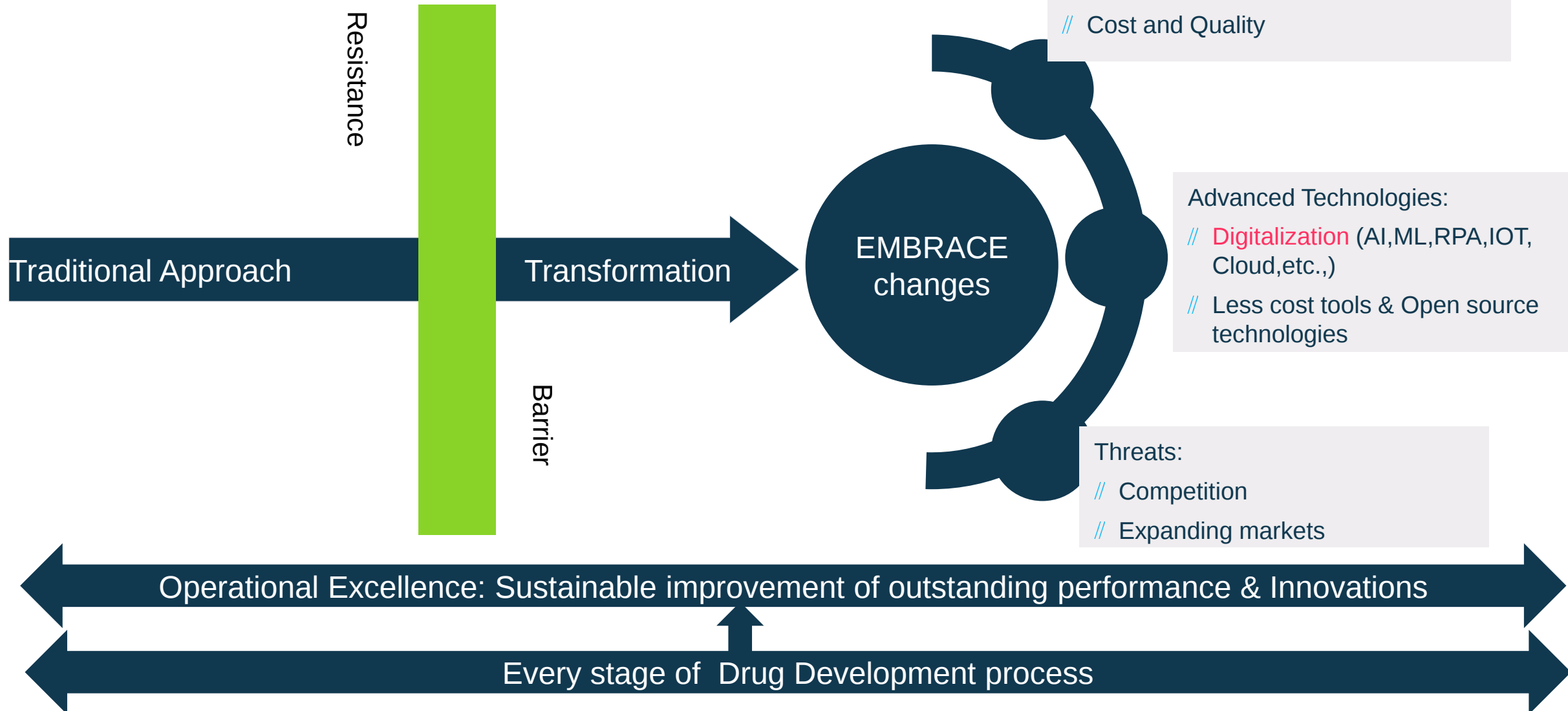
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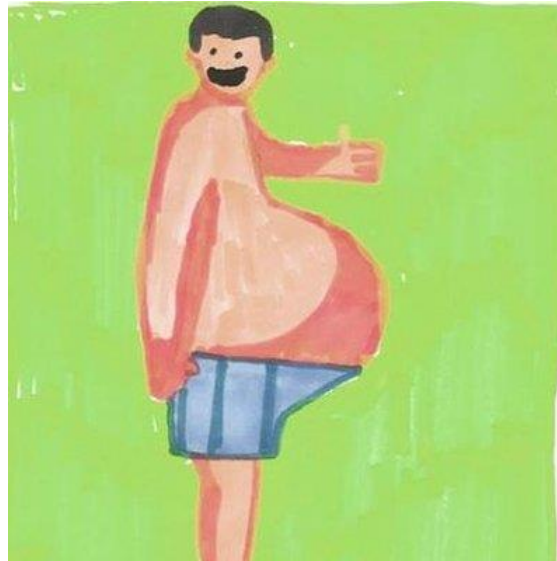
Drug development is a highly-regulated, long and costly endeavour with a low probability of success

## Introduction ( 1 of 2)



## Introduction (2 of 2)

When?



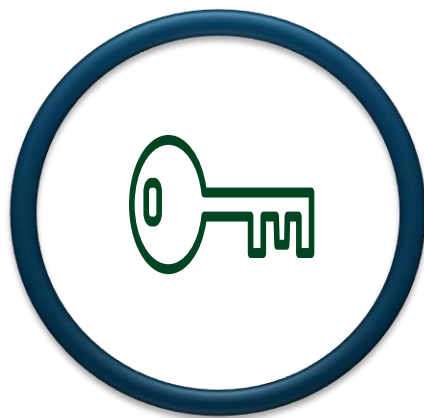
**WHY NOT?**



TAKE ONE SMALL  
**ACTION**

# Case-Study 1: Why So many Interim Analysis?

Ask why?



- 5 Year Study
- 4 Interim Analysis per year
- 150 outputs
- 3 FTE dedicated

**?**  
3 Internal + 1 external

Dynamic Dashboards  
for Internal + Excel  
reports  
(also helped in Data Cleaning)

## Reduction:

- // Biometrics (Stat, Programming, DM) effort
- // Resource Utilization
- // DM -> Less Snapshots/DBL
- // Time and Cost
- // Etc.,

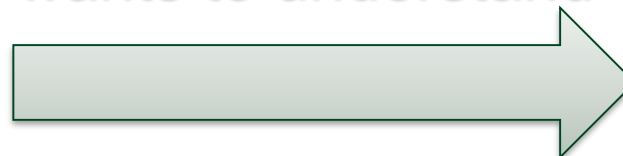
# Case-Study 2: Challenge Status Quo?

Established Medicine:



Pharmacovigilance

wants to understand



**ADVERSE EVENT**

42 AEs \* 5 Studies



LEGACY  
DATASETS

& MedDRA  
Mapping

210 Tables\*

Statistical Model  
involved with 'p'  
values & CI  
displayed

3 Months + 2 FTE



1 Table

Only Frequency

1 Week + 0.5 FTE



## Case-Study 4: Terminated clinical trial





# Potentials options:

cutting down by 25%: Is that a dream or a reality?

The best investment today would be to invest in themselves and getting trained on the technologies for the future such as Data Science.



## Measurements:

**“Measurement is the first step that leads to control and eventually to improvement. If you can’t measure something, you can’t understand it. If you can’t understand it, you can’t control it. If you can’t control it, you can’t improve it.”**

- [H. James Harrington](#), Author & Management Mentor

## Process Improvements:

// Application of Sixsigma : Eliminating waste  
**TIMWOODS** method

(**T**ransportation, **I**nventory, **M**otion, **W**aiting, **O**ver-production, **O**ver-processing, **D**efects, and **S**kills )

## Collaboration:

- // Within organization/functions/Institutions
- // Health Authorities
- // Connect with Social forums (PhUSE, CDISC, etc.,)

## People Development: (Unleash the power of potentials)

- // Leadership/People Manager:
  - // Six-Sigma; reverse mentoring; technology awareness
- // Associates:
  - // Embrace changes (technology, business strategy, processes);
  - // Solve problems (opportunity)
  - // Work towards First Time Right
  - // Training on Quality review
  - // **“Learning through networking”**

## Technology Development:

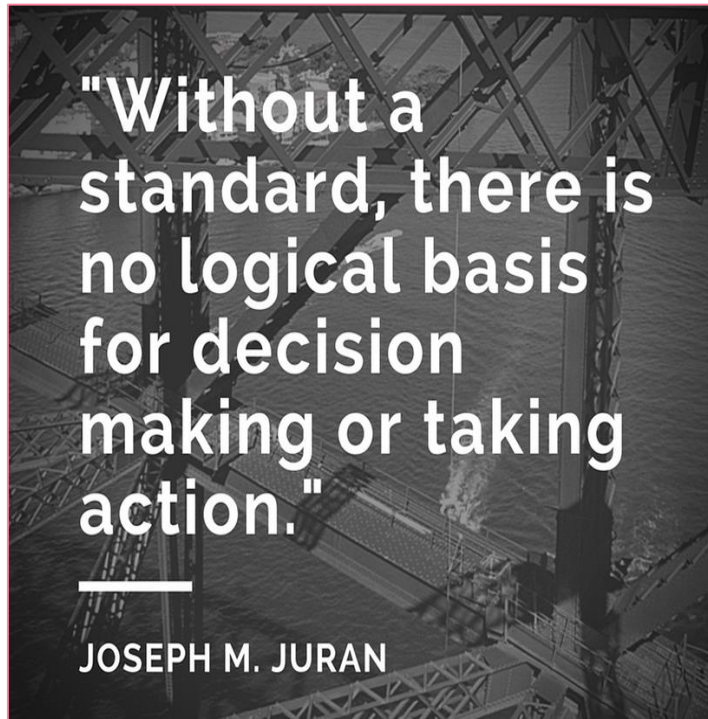
- // Explore new technologies
- // Look for options/open sources
- // AI/ML/RBA/digital

## Data Sciences in Drug Development :

- Leverage data

**Dream  
or  
Reality  
?**

## Conclusion:



DREAM or REALITY?



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*Thank you!*



**Bye-Bye**

