



# Clinical Pharmacology Project Management Support

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I was born in the USA. My father is Spanish, my mother is Romanian, though grew up in Barcelona, Spain, since I was 6 months old. I studied in Florida, lived in France for a year, spent 18 years in Australia, and returned to hometown of Barcelona 2 years ago.



# Agenda

- What is Project Management
- Submission Project Management Office Focus Areas
- Submission Project Management Activities
- Project Management Tools
- Lessons Learned
- Impacting future submission project management



## What is Project Management?

A discipline of planning, organizing, and managing resources to achieve specific goals and meet specific success criteria within a specified timeframe.

We apply knowledge, skills, tools, and techniques to project activities to meet the project requirements.



Initiation



Planning



Execution



Monitoring and Controlling



Closing



# Submissions Project Management Office Focus Areas

PM core responsibility: active project management, oversight, tracking and reporting of projects, Tracking of project implementation, risks, lessons learned, RACI and meeting minutes.



External: Supporting interactions with Health Authorities  
Internal: Publications, Conferences, and Regulatory Submission



Strategic Initiatives include; accelerated submission activities, and great place to work initiatives



Process Improvements include; Process mapping, establishing and tracking operational KPIs



Internal tracking tools, Office Timeline Pro+, MS Project, Visio, CoPilot, ChatGPT, others as needed.



# Submissions Project Management Office Activities

Submissions Project Management Office (SPMO) supports regulatory submission projects in preparing Modules which include summaries of: Clinical Pharmacology, Biopharmaceutics, Bioanalytical, Population pharmacokinetics (PopPK), Exposure-Response of Efficacy and Safety and Integrated Summary of Immunogenicity (ISI). SPMO also supports teams in accelerating submission timelines.

Pharmacokinetic (PK)  
and Immunogenicity  
(ADA) for clinical study  
report

Population  
Pharmacokinetic  
Analysis

Exposure-Response  
Analysis

Pharmacodynamic  
Biomarker Analysis

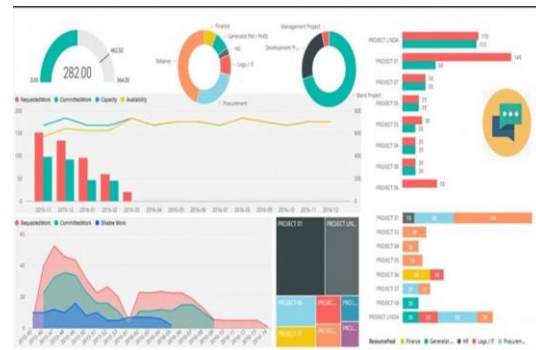
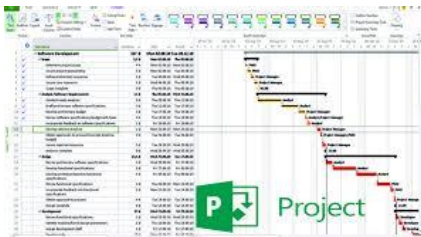
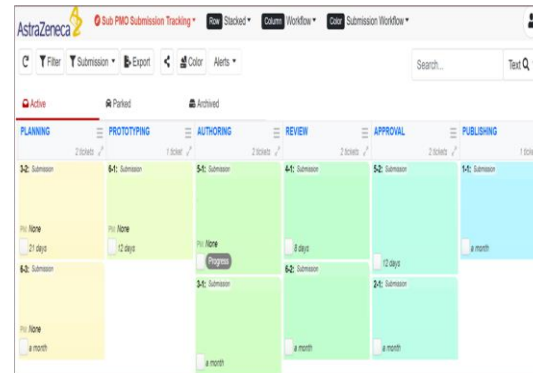
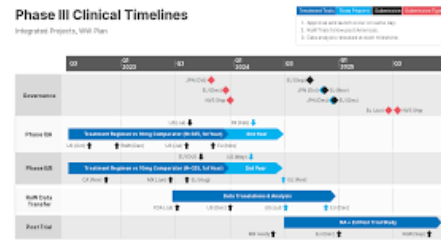
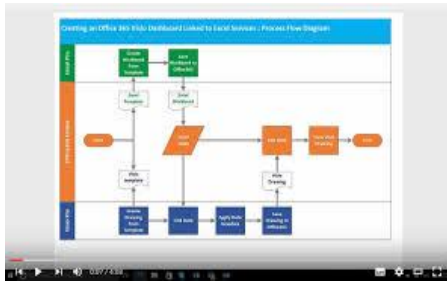
Bioanalysis

Other project support may include developing a Communication Strategy and Plan, coordinating responses to Health Authority Questions, and Advisory Board coordination.



# Project Management Tools

- ✓ Gathering and reporting
- ✓ Timeline Creation
- ✓ Sources of Information Software
- ✓ AI



Planisware

## Data Gathering/compiling in tracking system:

- ✓ project updates on regulatory submissions,

Reports are centralized and automatically generated from tracking system to another to create a report.

## Benefits:

- minimizing inadvertent human errors
- monitoring regulatory deliverables timelines, identifying projects at risk early on,
- combining data from various sources,
- providing high quality regulatory submissions reports



# Lessons Learned process in a Submission Project



- The process below is used to capture Lessons Learned after a submission to a Health Authority has been completed

## Initiating and Preparation

- Areas for Lessons Learned evaluation are identified.
- Questionnaires are prepared and sent to team members.
- Gathering the Responses are collected.
- A presentation based on questionnaire results for Lessons Learned workshops is created.

## Workshops

- Presentation is conducted based on Lessons learned questionnaire responses collected.
  - Results and recommendations are reviewed, discussed and approved during group workshops.

## Lessons Learned Repository and database update

- The Lessons Learned Repositories established, so the knowledge can be shared.
- Storing the presentations with conclusions and recommendations in SPMO Lessons Learned repository and global lessons learned repository.

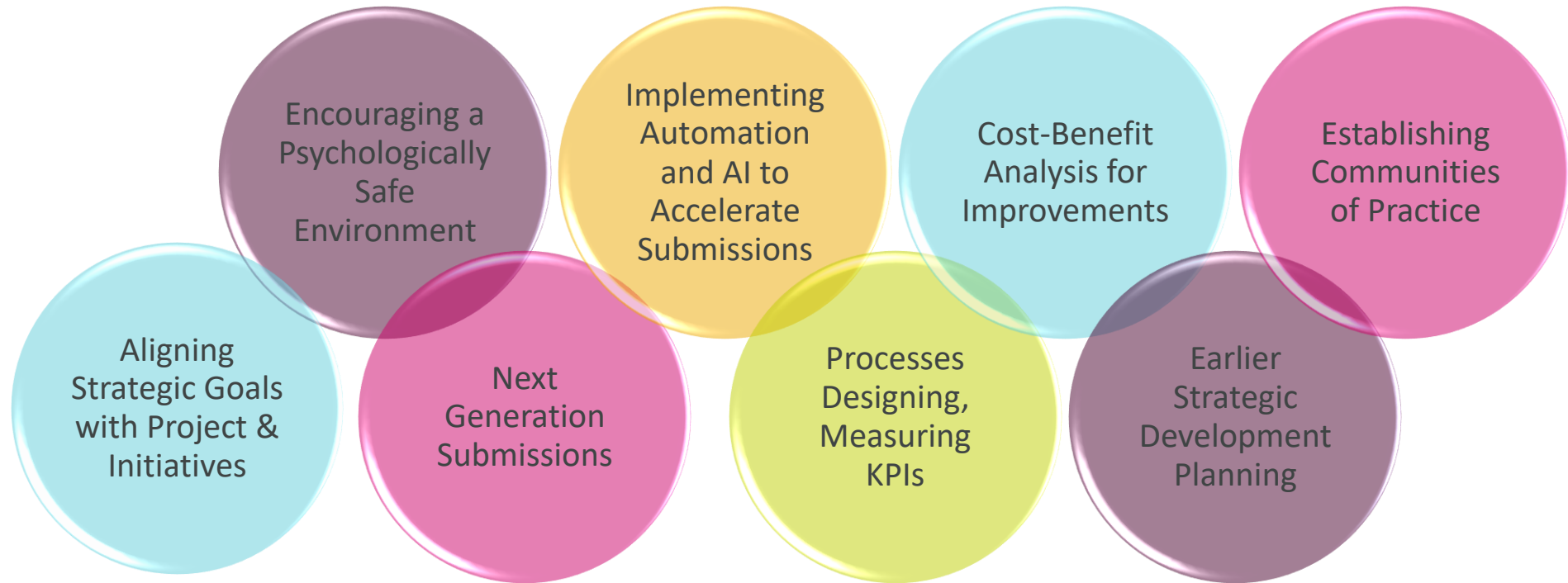
## Lessons Learned Closure

- The team's insights are captured and collated for a presentation to the wider team.
- Final presentations are stored in a SharePoint site, which is accessible to upcoming Submission teams for strategy planning.





# Current Project Management Activities Impacting the Future



To conclude...

Effective project management in Clinical Pharmacology ensures that clinical trials and submission projects are conducted efficiently, ethically, and in compliance with all regulatory requirements, ultimately leading to the successful development of new therapies.





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