2016 Good Registration Management Regulatory Science Center of Excellence Pilot Workshop

Planning of Application

Moderator: Jin Shun, AbbVie

Speaker: Thean Soo Lo, J&J

Sannie Chong, Roche

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Agenda

10:00~10:05	Speaker introduction	Jin Shun
10:05~10:10	Brief introduction	Jin Shun
10:10~10:20	What do we want	Jin Shun
10:20~10:45	What do we need	Thean Soo Lo
10:45~11:10	How do we do it	Sannie Chong
11:10~11:20	Q&A	Sannie Chong
11:20~12:00	Case study	ALL

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APEC GSubP Guideline

2. PRINCIPLES OF GOOD SUBMISSION

1. *Strong Scientific Rationale and Robust Data with Clarification of Benefit-Risk Profile*
2. *Compliance to Up-to-d*
3. *Well-Structured Submi Appropriate Cross-refe*
4. *Reliability, Quality, Inte Submission Document*
5. *Effective and Efficient*

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3. MANAGEMENT OF SUBMISSION

- *Planning for submission*
  - *Start discussion on submission st* ***product development***
  - *Use* ***support tools*** *effectively e.g.*
- *Preparation and Submission o*
  - *Provide general instructions on* ***compiling and submission***
  - *Encourage creating* ***SOPs***
- *Quality Check*
  - *Provide instructions on QC at w*
    - ✓ ***Study reports and summ***
    - ✓ ***Submission dossier, Elec***

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4. COMMUNICATIONS

- *Communications with review authorities*
  - *Make effective use of* ***pre-/post- submission meetings***
  - *Manage* ***inquiry and response*** *appropriately e.g. clarifications, timeline management*
- *Communications amongst applicants*
  - *Confirm* ***operation model, role and responsibility*** *of the submission team & members*
  - *Establish* ***standard working procedure and communication platform***

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APEC GSubP Guideline

2. PRINCIPLES OF GOOD SUBMISSION

1. Strong Scientific Rationale and Robust Data with Clarification of Benefit-Risk Profile
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5. Effective and Efficient

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3. MANAGEMENT OF SUBMISSION

- Planning for submission
  - Start discussion on submission strategy from **early stage of product development**
  - Use **support tools** effectively e.g. check-list, template, glossary
- Preparation and Submission of Application Dossier
  - Provide general instructions on **report/summary writing, compiling and submission**
  - Encourage creating **SOPs**
- Quality Check
  - Provide instructions on QC at writing/revision/translation for,
    - ✓ **Study reports and summary documents**
    - ✓ **Submission dossier, Electronic dossier**

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vith review authorities
of **pre-/post- submission**

nd response appropriately
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amongst applicants
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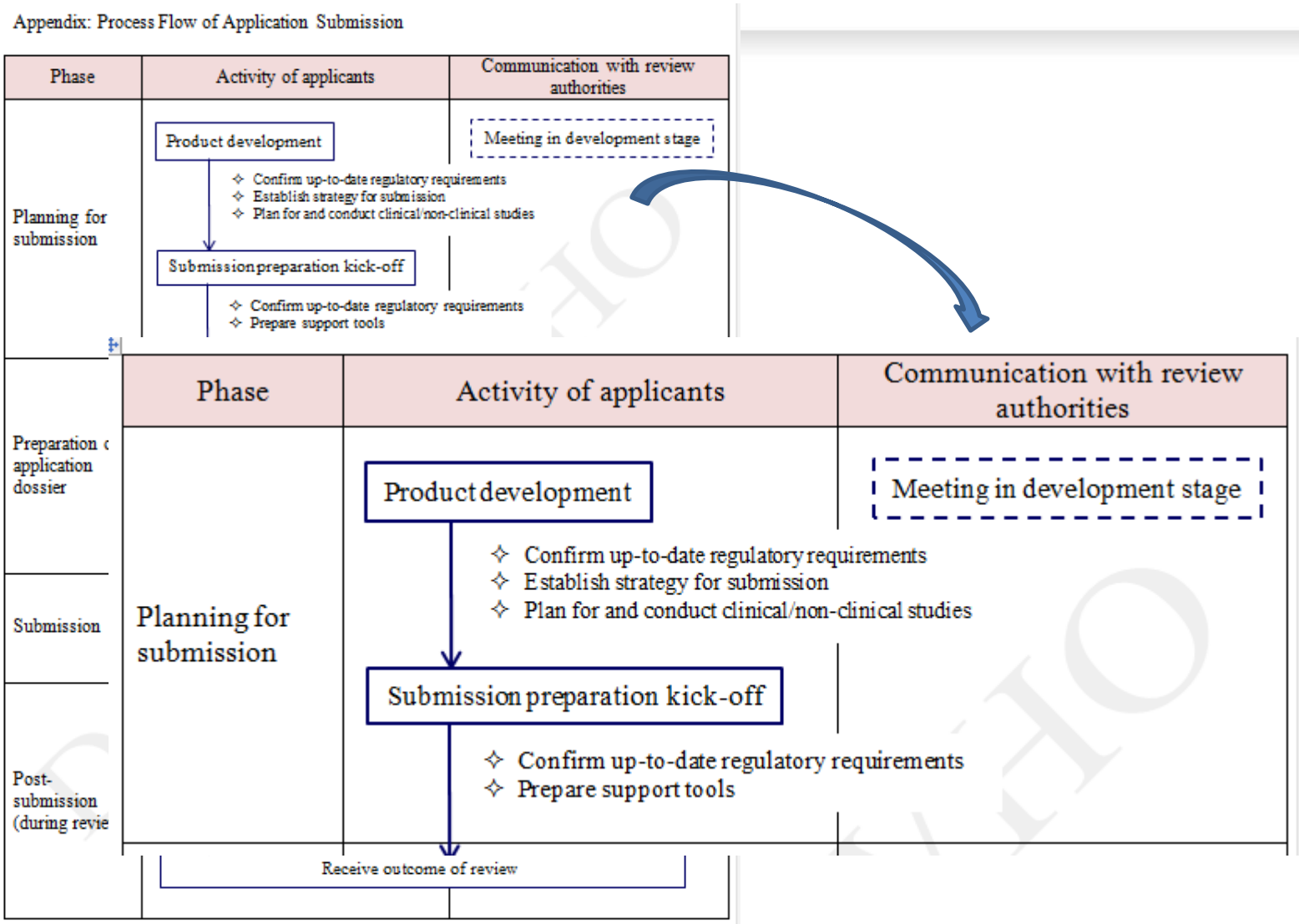
APEC GSubP Flowchart



Planning of submission

- Purpose of planning
  - Give clear strategic direction for submission
  - Prepare necessary tools for submission
  - In compliance with regulatory requirements

Planning of submission (prior to dossier preparation)

- What do we want?
- What do we need?
- How do we do it?

Planning of submission (prior to dossier preparation)

–**What do we want?**

–What do we need?

–How do we do it?

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Planning of submission

What do we want?

16-Nov-2016

Jin Shun
Director, Regulatory Policy & Intelligence, JAPAC
AbbVie

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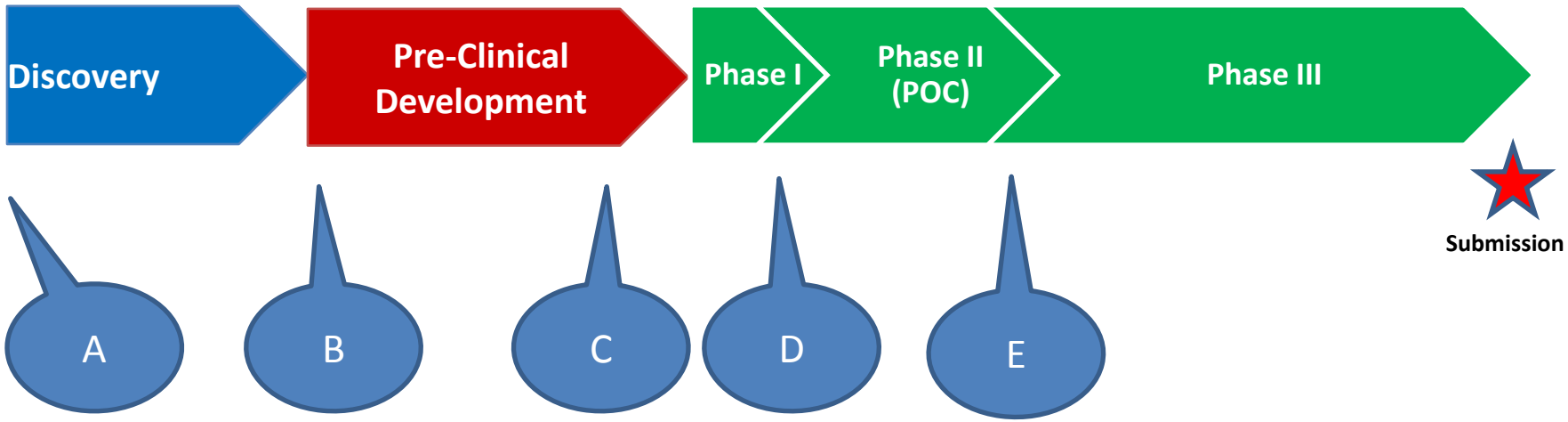
When do we start the planning for submission?



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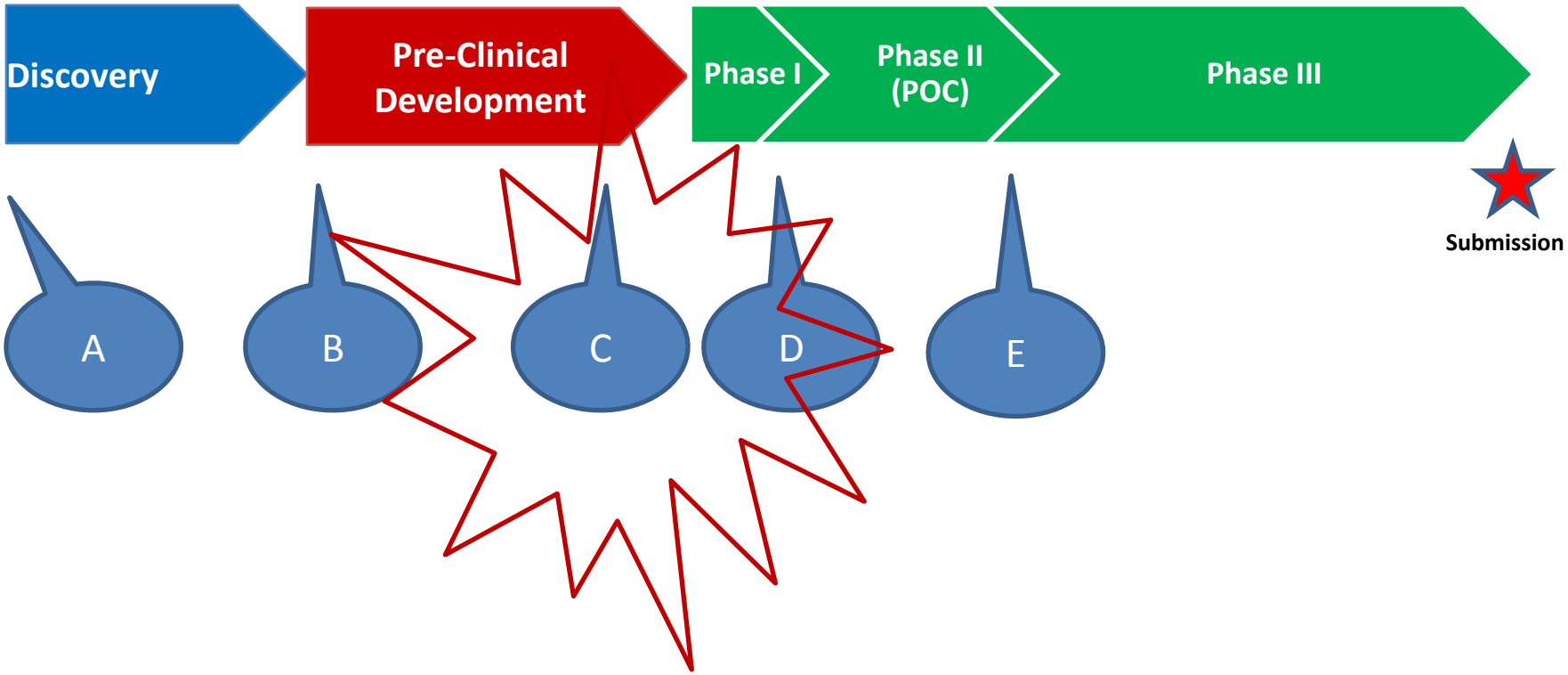
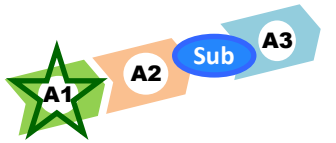
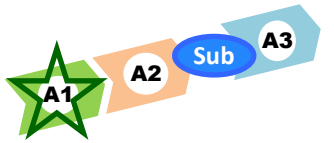


Target Product Profile (TPP)



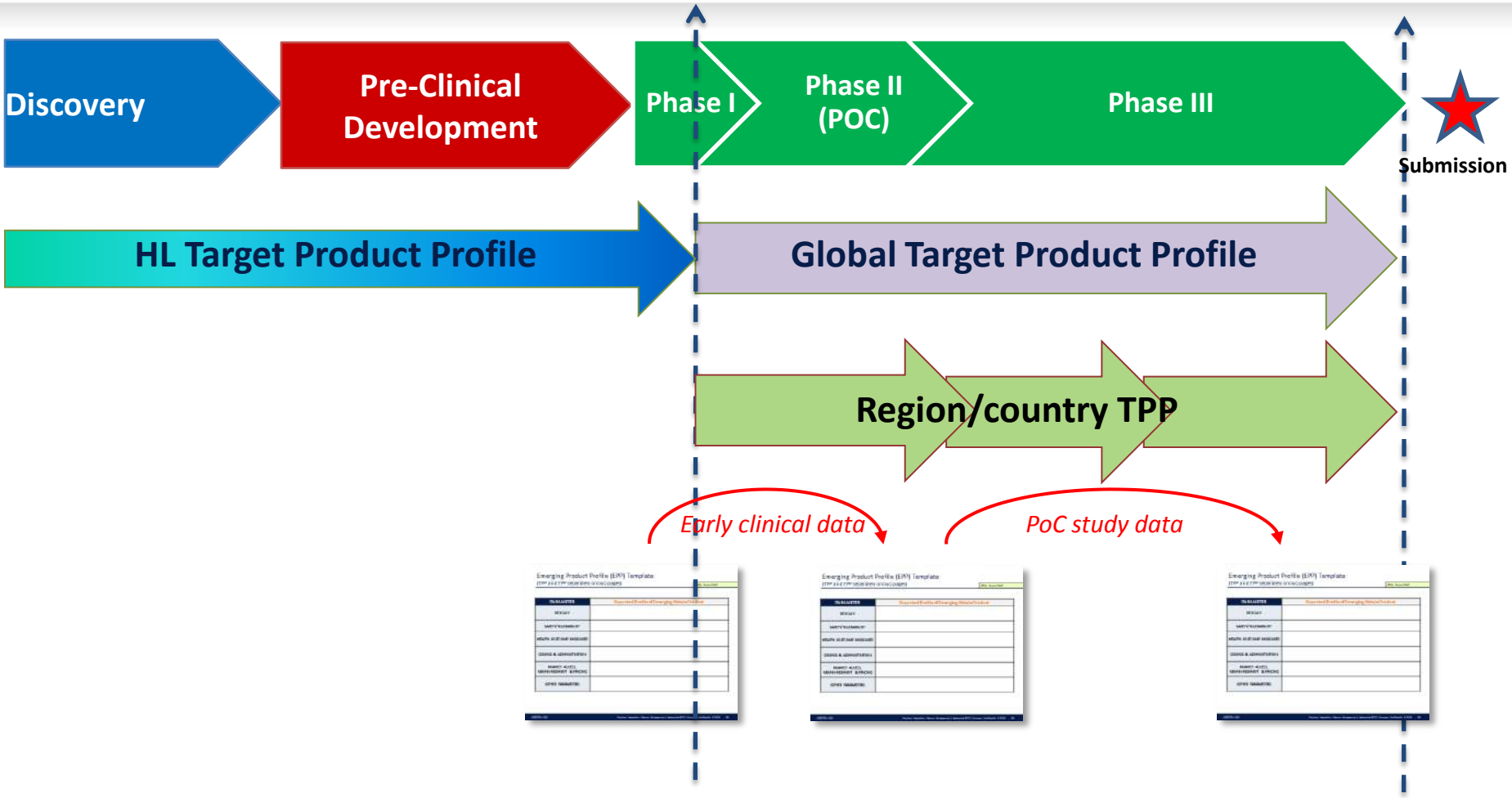
- Definition
  - Set the “goalposts” for what we believe will be required to be successful in the marketplace and thus informs our clinical development program and/or other evidence-generation activities for specific indications
  - Anticipate requirements for future products that will launch in 5 to 10 years
- High-Level TPP
  - Can be developed as early as the pre-clinical stage
  - Information about what any new product would have to aim to deliver to demonstrate meaningful clinical benefit in support of a differentiated value proposition in a disease state
- Global TPP
  - The Global TPP that would apply to any new drug in an indication will be required prior to Phase II
  - Reflects the targeted commercially viable profile
  - Cover all key regions in the world
  - Should change only when substantial environmental or competitive events take place

Target Product Profile (TPP)



- Regional or country TPP
  - Support Clinical and Commercial decision-making, and informs forecasts based on current data about the asset
  - Defines expected local attributes of an investigational drug candidate
  - Based on existing pre-clinical, clinical, epidemiologic and other data available at the time
  - Reflect the profile of the product most likely to launch, incorporating the latest local information available
  - Be informed by the continuously growing body of clinical evidence, and may change over time

TPP generation process



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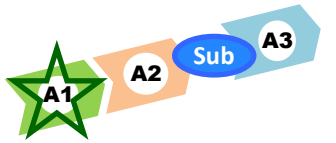
Target Product Profile (TPP) Template



EXAMPLE

Date Completed:

PARAMETER	Expected Profile of Target Product
EFFICACY	
SAFETY/TOLERABILITY	
HEALTH OUTCOME MEASURES	
DOSING & ADMINISTRATION	
MARKET ACCESS, REIMBURSEMENT & PRICING	
OTHER PARAMETERS	

Reflects the profile of the product most likely to launch, incorporating the latest data from all functions

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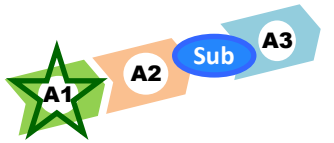
Key consideration of TPP

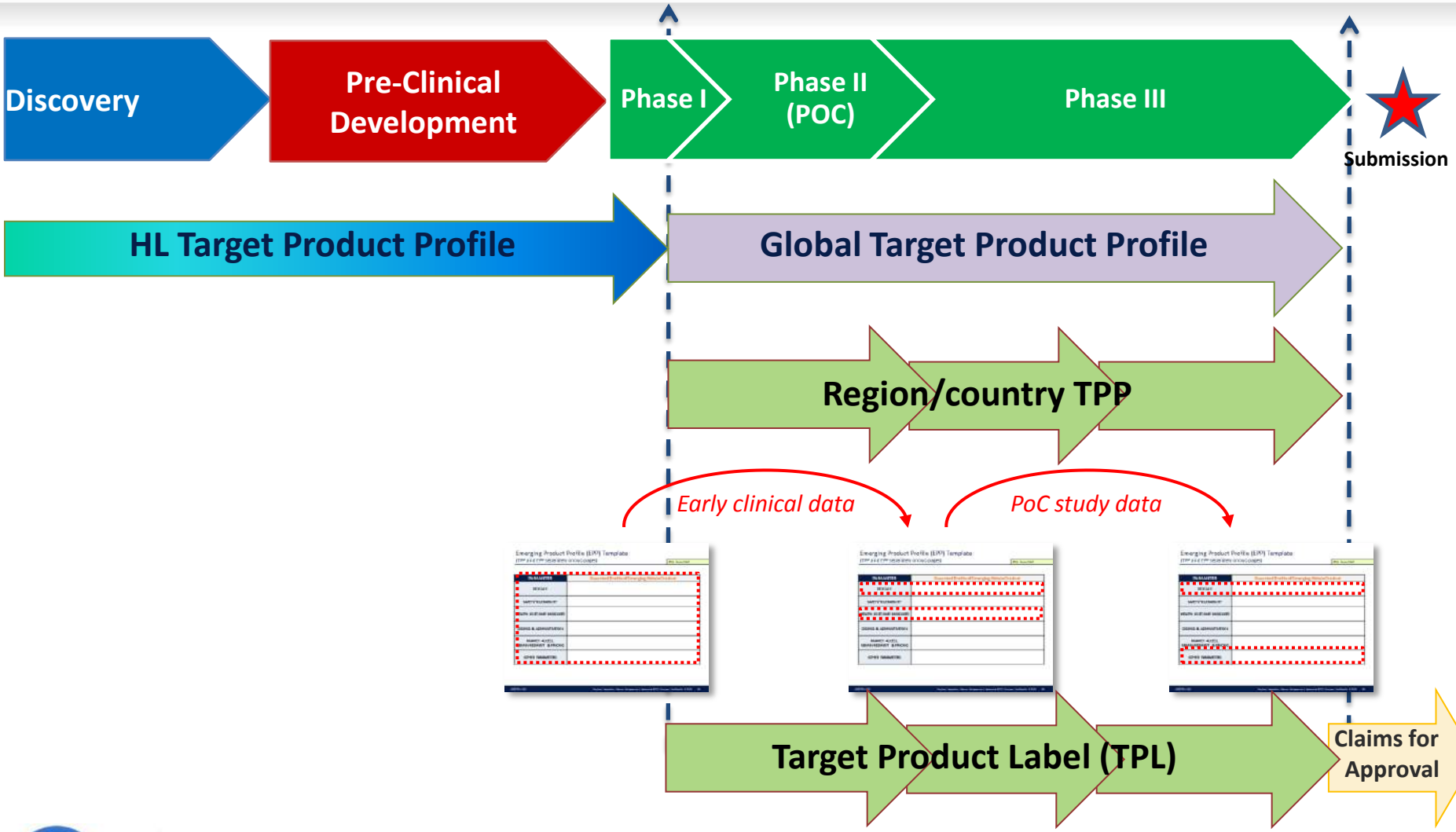
- Can include low, mid, high case in the global TPP for different potential clinical outcomes.
- Possibility for regional/country specific ones
- Global TPP will not be changed frequently unless significant change happened such as regulatory environment change
- Regional/country TPP can be changed based on the accumulation of clinical evidence

Target Product Label (TPL)



- Begins by capturing categories of claims, but, does not define exact language to be used, supported by proposed and/or completed clinical protocols
- Evolves into claim language representing the best understanding of what to expect to use in materials based on prospective label
- Ends in claim language which is “ready to use” in materials- refined and specific based on anticipated label
- Used to create the Developmental Core Data Sheet (DCDS), then, the Company Core Data Sheet (CCDS)

TPP/TPL generation process



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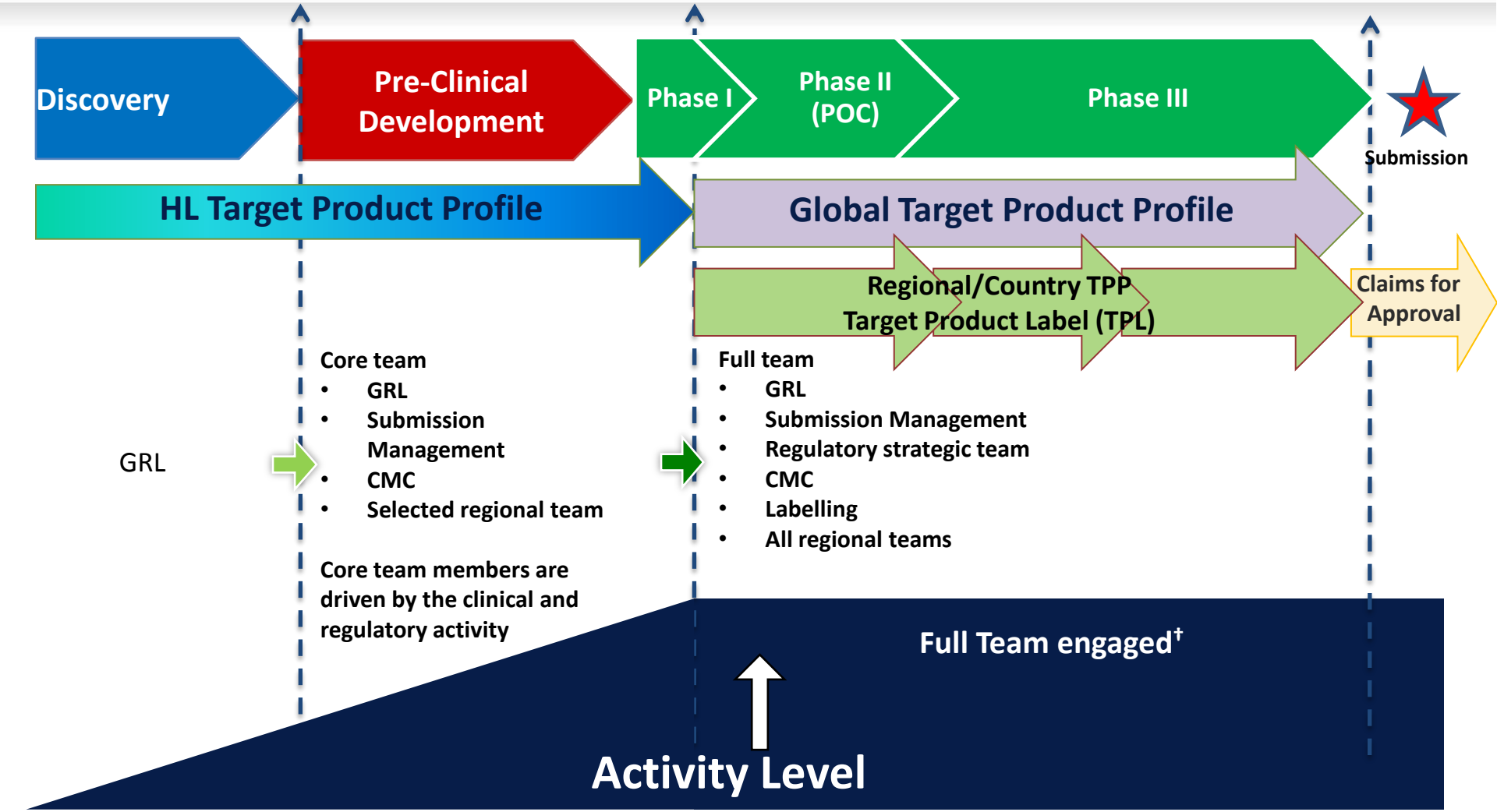
Organizational preparation

- Key regulatory related functions:
  - Global regulatory lead
  - Submission management
  - CMC
  - Regional/Country team
  - Regulatory strategy team
  - Labelling
- Other important functions:
  - Commercial, Safety, Medical, Clinical, PM
- The level of involvement is increasing with the progress of development

Organizational preparation



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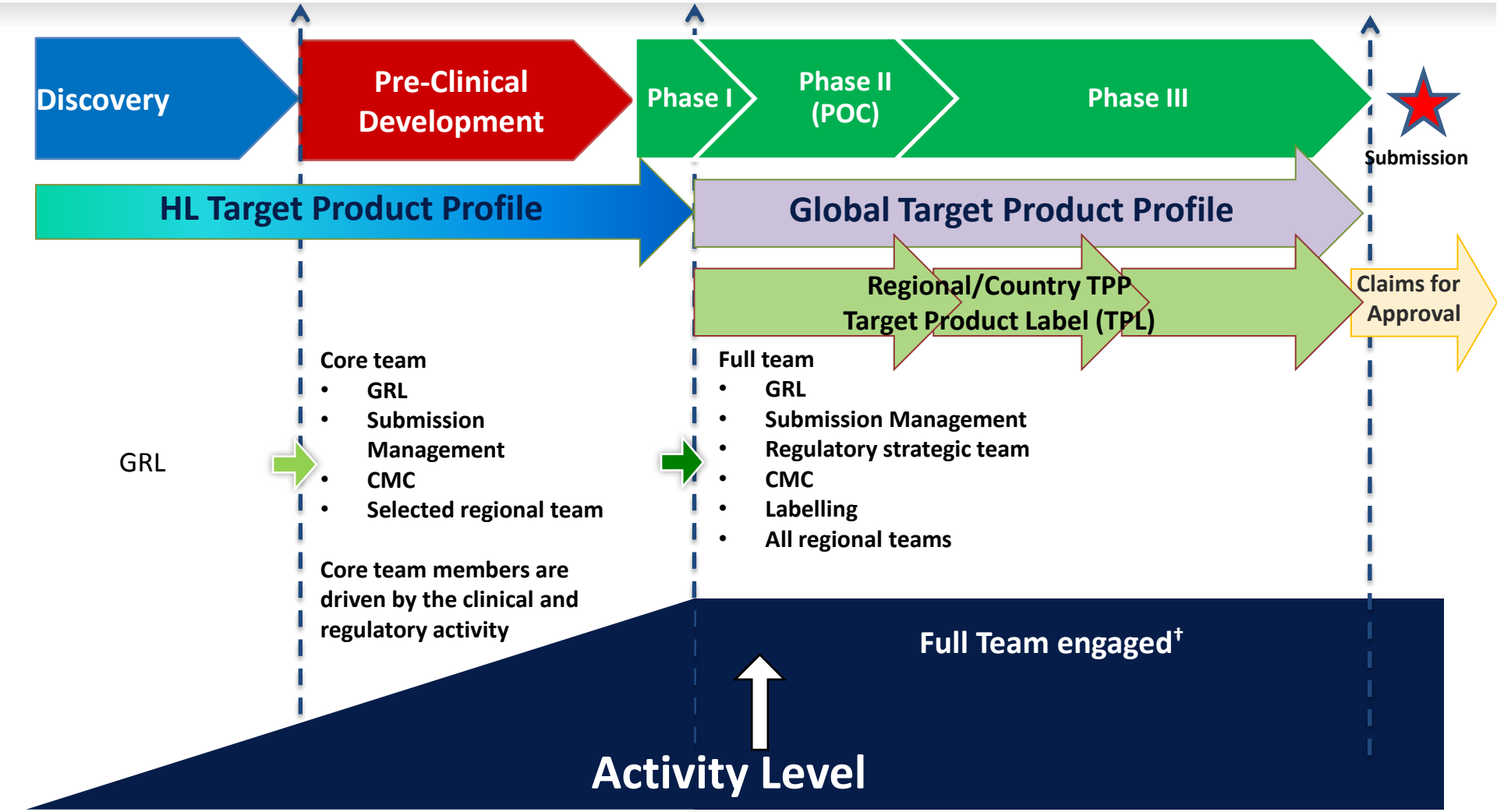
Organizational preparation



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Planning of submission (prior to dossier preparation)

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- **What do we need?**
- How do we do it?

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Planning of submission

What do we need?

16-Nov-2016

Thean Soo (TS) Lo
AP Lead, Global Regulatory Policy & Intelligence
Janssen J&J

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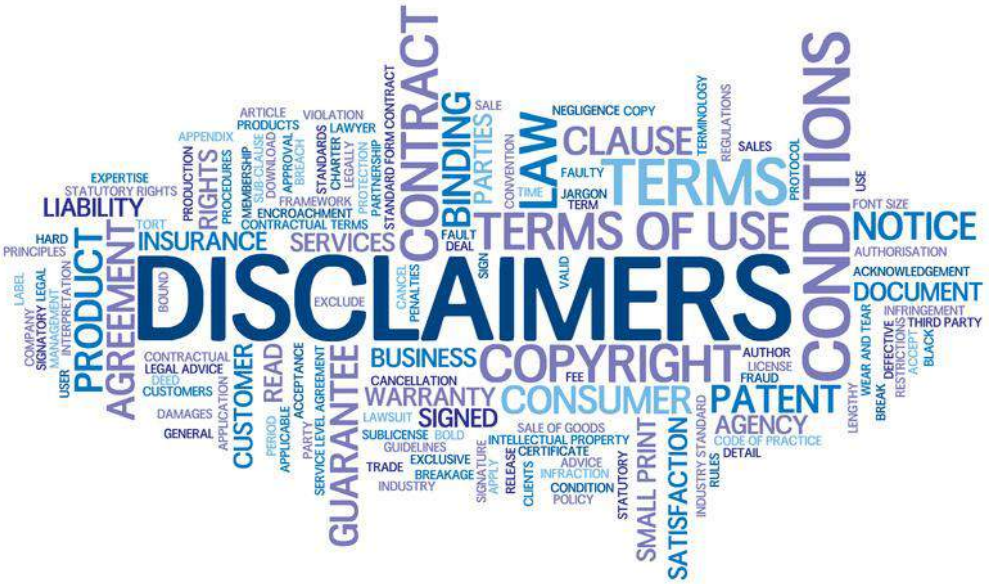

…any opinions that may be shared by the speaker are his and not necessarily represent the views of the company….

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What do we need?

Bad Planning → Good Planning

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What do we need?

The Needs

The Tools

The Activities

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What do we need?

Building Your Submission Kit

The Needs

The Tools

The Activities

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End-to-End Product Lifecycle = End-to-End RA Involvement

R&D

Key Activities

- Regulatory Strategy
- Regulatory Intelligence
- Health Authority meetings
- Draft Labeling
- Phase I Deliverables

CMC Process development

EARLY DEV to PH1

- Finalize strategy for health authority interactions
- Plan for submission
- Phase II Deliverables
- Pediatric investigational plans (PIPs)

CMC Tech transfer & manufacturing

PH II a/b

- Plan for submission
- Prepare for Advisory Committee
- Phase III deliverables

CMC Process validation & submission planning

PH III

SUBMISSION & APPROVAL

- Align submission plan with launch strategies
- File registration
- Plan for health authority questions
- Plan for launch
- Negotiate labels

Commercial

Supply Chain

POST-APPVL POST-DEV

- Maintain License/ Lifecycle Management Activities
- Maintain Labels
- Support Phase IV commitments

What do we need?

Building Your Submission Kit

The Needs

The Tools

The Activities

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What do we need?

The Needs

1. Regulatory Strategy
2. Regulatory Intelligence
3. Health Authority Meetings
4. Draft Labeling
5. Plan for Submission
6. Finalize Strategy for Health Authority interactions

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What do we need?

Building Your Submission Kit

The Needs

The Tools

The Activities

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What do we need?

1. Regulatory requirements & guidance
2. Regulatory intelligence database
3. Competitive intelligence
4. Planning of pre-submission meeting
5. Project teams
6. SOPs
7. Dossier structure & checklist

The Tools

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What do we need?

Building Your Submission Kit

The Needs

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The Activities

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What do we need?

"The Activities"

- ✓ Review relevant GL for project – eg pathways (expedited, accelerated, standard, abridged, full review, specific GL
- ✓ Country specific requirements, more subtle types of information, soft intelligences, past experiences, timelines, market information
- ✓ Competitor list, competitor strategies, define own strategy (timelines, TPP, etc ..)
- ✓ Gathering what you need to prepare for a pre-submission meeting, relevant GL, TPP, tentative strategy
- ✓ Cross functional, communication, consulting, collaboration with project team members to define strategy – marketing, medical affairs, logistics, CMC
- ✓ Review relevant SOPS, internal GL, develop project specific SOPS, if necessary
- ✓ Using generic template, define product specific dossier structure, review product profile, module 1, 2, 3, 4 data

The Activities

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What do we need?

Building Your Submission Kit

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What do we need?

The Needs

1. Regulatory Strategy
2. Regulatory Intelligence
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The Tools

1. Regulatory regulations/guidance
2. Regulatory intelligence database
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7. Dossier structure & Ch[illegible]list

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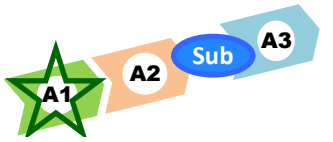

Your Submission Kit

The Needs

1. Regulatory Strategy
2. Regulatory Intelligence
3. Health Authority Meetings
4. Draft Labeling
5. Plan for Submission
6. Finalize Strategy for Health Authority interactions

The Tools

1. Regulatory regulations/guidance
2. Regulatory intelligence database
3. Competitive intelligence
4. Planning of pre-submission meeting
5. Project teams
6. SOPs
7. Dossier structure & Checklist

The Activities

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What do we need?

"The Needs"	"The Tools"	
1. Regulatory Strategy	1. Regulatory requirements & guidance 2. Regulatory intelligence database 3. Competitive intelligence 4. Planning of pre-submission meeting	5. Project teams 6. SOPs 7. Dossier structure & checklist
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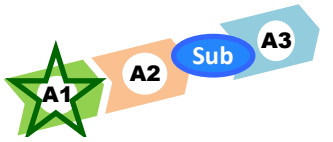

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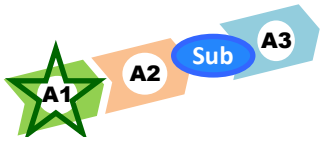

"Needs"	"Tools"	"The Activities"
1. Regulatory Strategy Sample strategy document content • Executive summary • Product background information • Project specific regulatory strategy • Project specific plan for risk assessment & mitigation • Global support plan • Global clinical development • CMC regulatory strategy • List of core documents required.	• Regulatory requirements & guidance	✓ Review relevant GL for project – eg pathways (expedited, accelerated, standard, abridged, full review, specific GL
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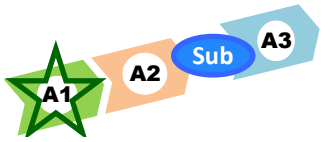

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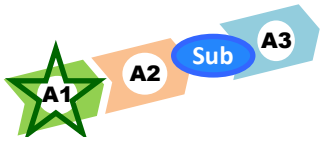

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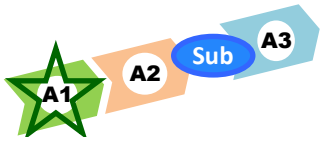

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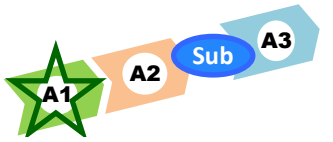
	• Dossier structure & checklist	✓ Using generic template, define product specific dossier structure, review product profile, module 1, 2, 3, 4 data

What do we need?



"Needs"	"Tools"	"The Activities"
6. Finalize Strategy for Health Authority interactions	• Regulatory requirements & guidance	✓ Review relevant GL for project – eg pathways (expedited, accelerated, standard, abridged, full review, specific GL
	• Regulatory intelligence database	✓ Country specific requirements, more subtle types of information, soft intelligences, past experiences, timelines, market information
	• Competitive intelligence	✓ Competitor list, competitor strategies, define own strategy (timelines, TPP, etc ..)
	• Planning of pre-submission meeting	✓ Gathering what you need to prepare for a pre-submission meeting, relevant GL, TPP, tentative strategy
	• Project teams	✓ Cross functional, communication, consulting, collaboration with project team members to define strategy – marketing, medical affairs, logistics, CMC
	• SOPs	✓ Review relevant SOPS, internal GL, develop project specific SOPS, if necessary
	• Dossier structure & checklist	✓ Using generic template, define product specific dossier structure, review product profile, module 1, 2, 3, 4 data

What do we need?

Building Your Submission Kit

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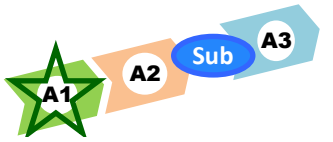
What do we need?



Your Submission Kit

The Needs

1. Regulatory Strategy
2. Regulatory Intelligence
3. Health Authority Meetings
4. Draft Labeling
5. Plan for Submission
6. Finalize Strategy for Health Authority interactions

The Tools

1. Regulatory regulations/guidance
2. Regulatory intelligence database
3. Competitive intelligence
4. Planning of pre-submission meeting
5. Project teams
6. SOPs
7. Dossier structure & Checklist

The Activities

- ✓ Review relevant GL for project – eg pathways (expedited, accelerated, standard, abridged, full review, specific GL
- ✓ Country specific requirements, more subtle types of information, soft intelligences, past experiences, timelines, market information
- ✓ Competitor list, competitor strategies, define own strategy (timelines, TPP, etc ..)
- ✓ Gathering what you need to prepare for a pre-submission meeting, relevant GL, TPP, tentative strategy
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Planning of submission (prior to dossier preparation)

- What do we want?
- What do we need?
- **How do we do it?**

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2016 Good Registration Management Regulatory Science Center of Excellence Pilot Workshop

Planning of submission

How do we do it?

16-Nov-2016

Sannie Chong
Head, APAC Technical Regulatory Policy
Roche

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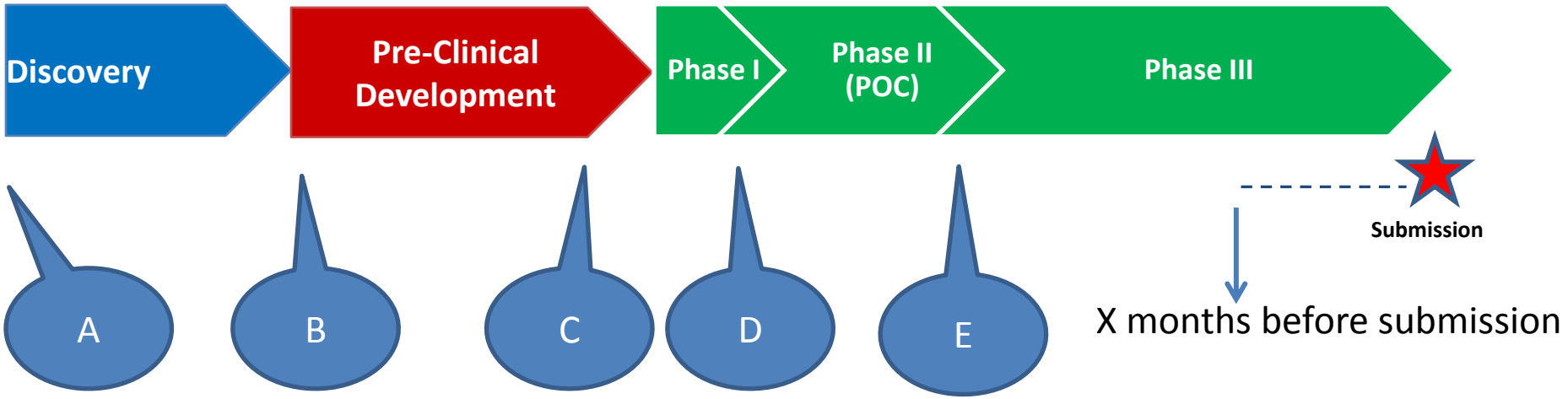
How to interpret the intelligence into strategic plan

How do we do it?



Strategic plan at various stages:

(1) Point C: Planning for submission: Consider a selected list of countries on top of ICH countries (Factors to consider include e.g. indication, etc.)

(2) During/after Phase II: Decision to expand (consider e.g. local trials, operation feasibility, etc)

(3) X Months before submission

(Factors to consider – see next slide)

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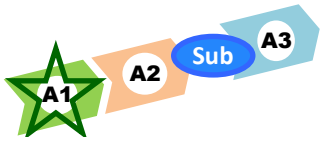
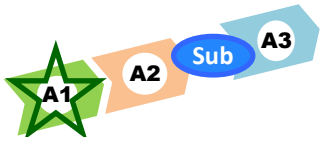
Interpret the intelligence into strategic plan
How do we do it?



X months before the submission ★

1. Strategic fundamentals
   - (a) ICH countries' requirements
   - (b) Local clinical data result/analysis
   - (c) CPP
   - (d) Country specific requirements
   - (e) Samples and Sourcing scenario

Interpret the intelligence into strategic plan How do we do it?



X Months before the submission ★

1. Strategic fundamentals

   (a) ICH countries requirements

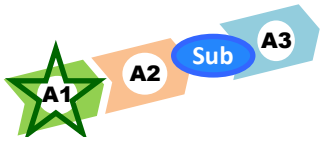
   – Why ICH? (Transparent, science-based, prior approval required (CPP), etc.)

   (b) Local clinical data and/or results/analysis

   (c) CPP – Exercise 1

Interpret the intelligence into strategic plan

How do we do it?



Exercise 1

(i) Trainee to list out CPP requirement in the country

- How many?
- Preferred country?
- Issued by country of origin or..?
- At the point of submission?
- Language?
- Others?

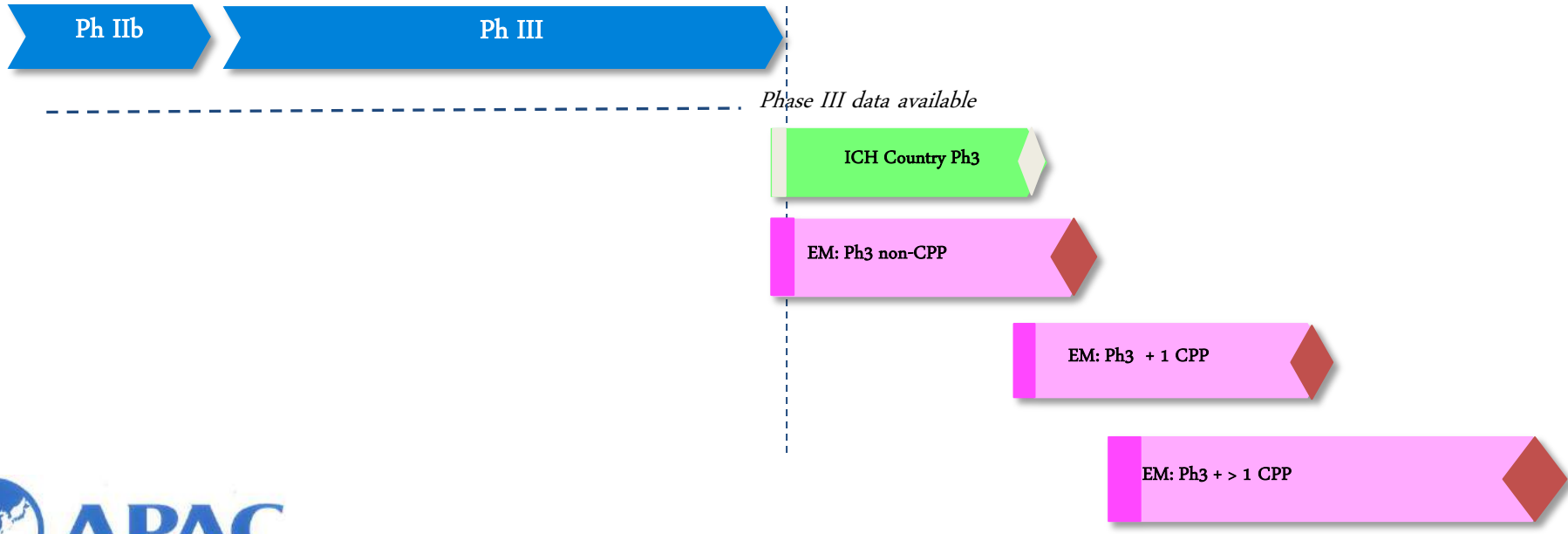
(ii) Trainee to share the CPP requirement with two other Trainees

(iii) Together, plan the submission priority based on CPP requirements in these countries

Interpret the intelligence into strategic plan
How do we do it?

Exercise 1 Discussion:

CPP requirement differs from country to country.
Use the intelligence when planning for submission.



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Interpret the intelligence into strategic plan
How do we do it?

Exercise 1 Discussion:

CPP requirement differs from country to country.
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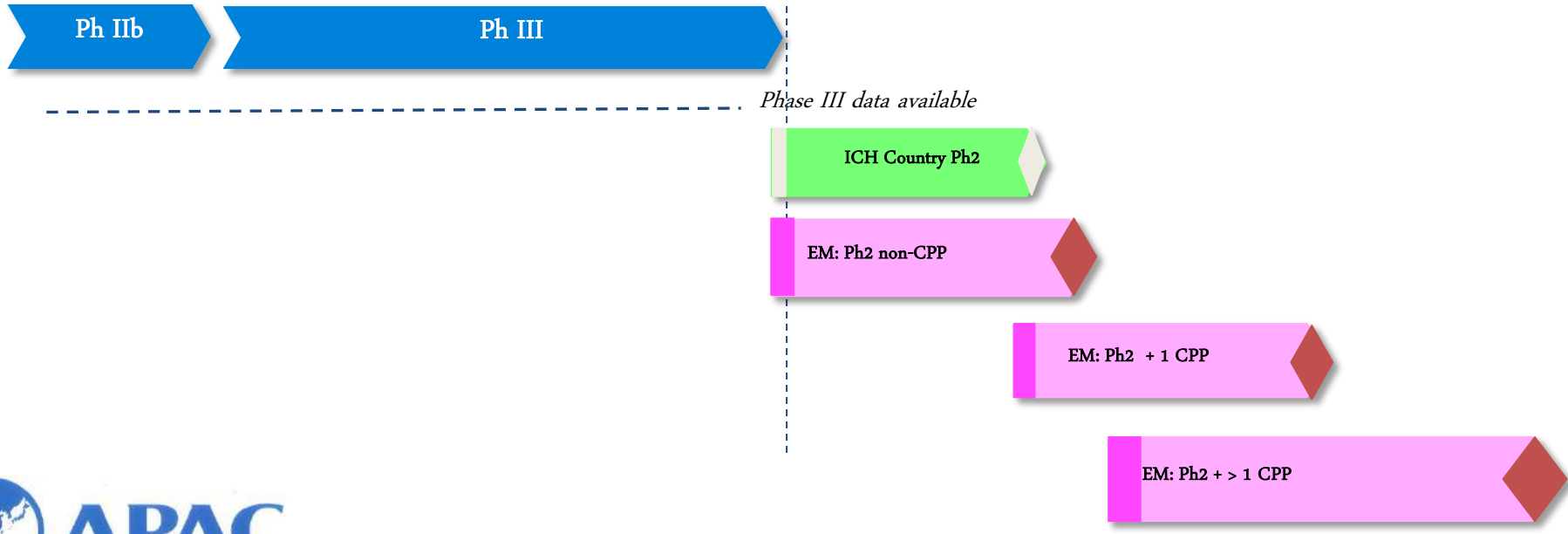

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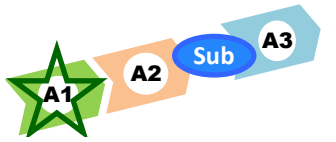
Interpret the intelligence into strategic plan
How do we do it?



X Months before the submission ★

1. Strategic fundamentals

   (a) ICH countries' requirements

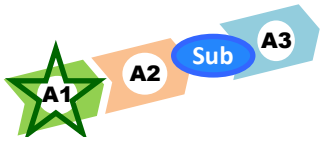
   (b) Local clinical data result/analysis

   (c) CPP

   (d) Country specific requirements

   (e) Samples and Sourcing scenario

Interpret the intelligence into strategic plan



How do we do it?

Exercise 2: Country specific requirements (CSR)

(i) Trainee to list the CSR in the country e.g.

- Electronic platform versus e-CTD
- CMC information e.g. full stability data
- Artworks: Wording of indication, actual carton box

(ii) Trainee to share the CSR with two other Trainees

(iii) Together, share the points to consider when planning the submission based on the CSR

(iV) Now go back to the submission priorities decided on exercise 1 and apply the CSR. Are the priorities still the same?

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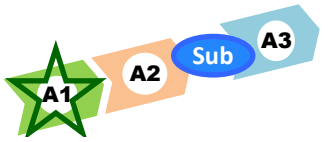
Interpret the intelligence into strategic plan



How do we do it?

Months before the submission ★

1. Strategic fundamentals

   (a) ICH countries' requirements

   (b) Local clinical data result/analysis

   (c) CPP

   (d) Country specific requirements

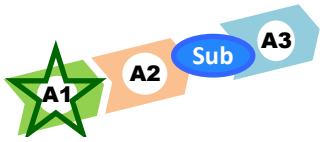
   (e) Samples and Sourcing scenario

   – Ordering samples

   – Shelf life remaining

   – Others considerations

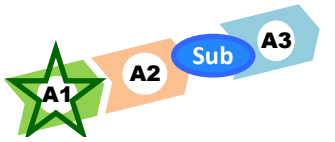
Interpret the intelligence into strategic plan



How do we do it?

1. Strategic fundamentals
2. Operational effectiveness
   - Success factor: Two-way engagement with affiliates and cross-functional partners
   - Formal resource allocation: country specific requirement can be planned for and requested earlier
   - Improved tools and processed: Support in place for country specific requirements
   - Publishing and operations process (HQ/Affiliates)
   - Pre-approval inspection
   - Intent to file tracker
   - Q&A/Approval tracking
   - Pre-submission meeting

Interpret the intelligence into strategic plan How do we do it?

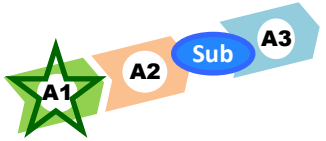


Planning for pre-submission meeting

- Meeting materials availability
- Module document ordering
- Capacity awareness: Team can only address questions after responses have been provided to ICH country
- Experience (affiliates)
- Communication plan
- Estimated timelines
- Points to consider due to limited data
- Regulatory pathway

Planning of submission (prior to dossier preparation)

- What do we want?
- What do we need?
- How do we do it?



Thank You!

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