Applicant-Specific Sessions A3
Effective communications

APAC EWG JPMA
Maya Kumano, Ph.D.
Kenichi Otani, Ph.D.
Akiko Ikeda

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Introduction

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Maya Kumano, Ph.D.

LEARNING OBJECTIVES:

1. To understand effective regulatory communication

2. To improve the communications with the stakeholders

Effective communications

Session Outline 1/2

	Contents	Output	Person in charge
9:00 – 9:05	**Introduction**	To share session objective	M.Kumano
9:05 – 9:20	**Ice Braking Game**	Recognize the importance of instruction and communication	M.Kumano
9:20 – 9:30	**GRP Communication introduction**	Explain effective communication Outline	M.Kumano
9:30 – 10:15	**Group Discussion**	Recognize to communicate effectively with stakeholders under considerations of each stakeholders' roles/responsibilities and gaps between the applicant and stakeholders	K.Otani
10:15 – 10:30	**Lecture 1**	Explain effective communication 1 •Understand how to communicate with internal stakeholders /external stakeholders •Key points to be considered for communication with stakeholders	K.Otani

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Session Outline 2/2

	Contents	Output	Person in charge
10:40 – 12:00	**Practice**	Find the practical effective communication with the stakeholder	A.Ikeda
12:00 – 12:10	**Lecture 2**	Explain effective communication 2 • The points to consider in inquiries/responses and meetings with the review authorities during review period • The points that applicants have to consider in the management of the timeline for response preparation	A.Ikeda
12:10 – 12:15	**Conclusion**		A.Ikeda

ICE Breaking Game

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GRP Communication introduction

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COMMUNICATIONS

- *Communications with review authorities*
  - *Make effective use of **pre-/post- submission meetings***
  - *Manage **inquiry and response** appropriately*

    e.g. clarifications, timeline management

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- *Communications amongst applicants*
  - *Confirm **operation model, role and responsibility** of the submission team & members*
  - *Establish **standard working procedure and communication platform***

Key considerations for the meeting with review authorities

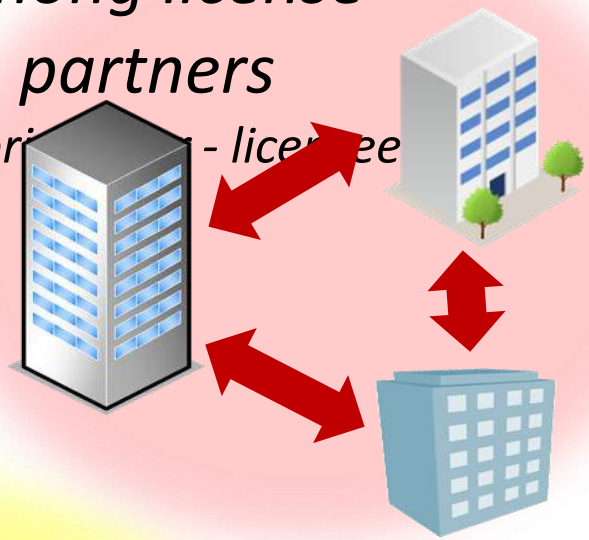
- Study and follow the defined rules and procedure for the meeting
- Clarify the purpose and discussion points
- Prepare good quality meeting materials
- Discuss based on reasonable scientific rationale
- Prepare and circulate meeting minutes/memo on discussion points and agreements
- Take appropriate follow-up measures on comments and advice received from the authorities

Communications amongst applicants

Among submission team members

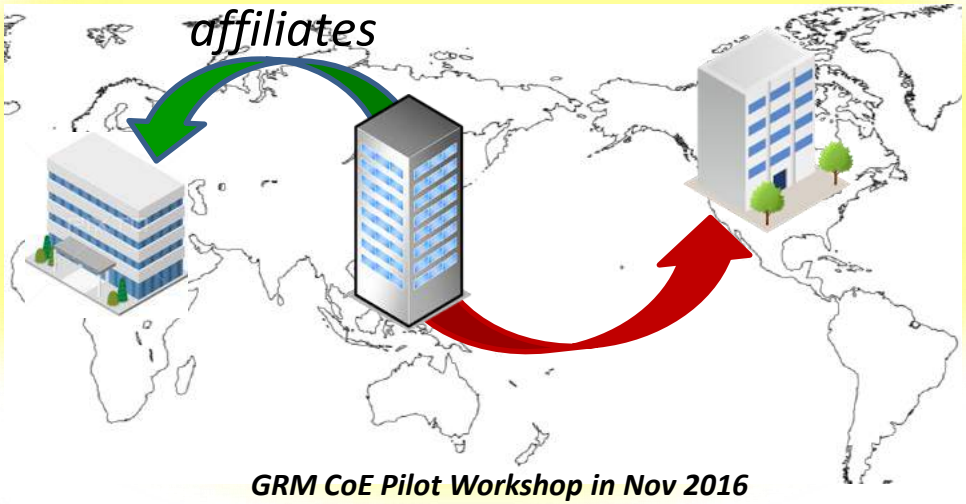
Among license partners

e.g. ori - licensee



Among regions

e.g. head quarters – affiliates



Group Discussion

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9:30-10:15 (45 minutes) Group Discussion

- Introduction: 2 min
- Group Work: 30min
  - ✓ 1st Group Work: 5min
  - ✓ Instruction: 5min
  - ✓ 2nd Group Work: 15-20min
- Each group to explain the outcome: 10min (3min x 2 groups)

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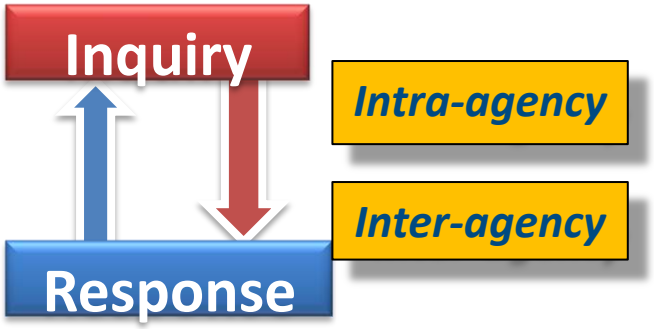
Points RA consider for interaction with HAs:

1. How to handle RA-related meetings, inquires from HAs and responses to HAs within/outside the company?

➢ focusing on ***stakeholders*** involved in the RA activity

Consultation /Meeting



2. How to prepare before a meeting, inquires from HAs and responses to HAs?

3. How to follow-up after the meeting, inquires from HAs and responses to HAs?

Importance of stakeholders on communication

- Communication is a complicated interaction with stakeholders
  - ✓ Regulatory professional needs to:
    - communicate effectively with stakeholders
    - be mindful of messages from stakeholders
    - persuade stakeholders
    - … …

Lecture 1
Explain effective communication 1

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Stakeholder analysis

- It is important for an effective communication
- It guides you to make decisions about:
  - ✓ *Roles and responsibilities of stakeholders*
  - ✓ *Ability of stakeholders to understand*
  - ✓ *Objectives of actions to stakeholders*
  - ✓ ...

For instance,

- Internal stakeholders
- External stakeholders

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Internal stakeholder -1/2-

- Regulatory professional needs to:
  - ✓ Clearly outline a purpose and desired goal
  - ✓ Make *internal stakeholders* know & give the information concisely
    - Board members of HQs and/or subsidiary
    - Global/Regional RA team
    - Cross-functional team, Clinical, Stats, Data management, CMC, PV, Intellectual Property, Marketing etc.
    - ▪ ▪ ▪

Internal stakeholder -2/2-

- Regulatory professional needs to:
  - ✓ Balance relationships between the *internal stakeholders*, considering the role and responsibility.
  - ✓ Foster trust and confidence in the internal team
  - ✓ Prepare for RA actions/documents (e.g. Briefing Book, materials for a meeting such as Presentation, potential Q&A, minutes) , cooperating with the *internal stakeholders*

External stakeholder -1/2-

- Regulatory professional needs to:
  - ✓ Communicate strategically, effectively, and persuasively with *external stakeholders*
    - Health authority (e.g. PJ manager, reviewer)
    - Contractors (e.g. CRO, translation company)
    - Corporate partners (e.g. licenser, licensee)
    - ・・・
  - ✓ Be transparent to the external stakeholders

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External stakeholder -2/2-

- Regulatory professional needs to:
  - ✓ Understand
    - Wants & needs of the *external stakeholders*
    - cross-cultural communication
    - components of formal/informal meetings with HAs
    - the intention of HAs' reviewers
  - ✓ Have abilities to negotiate, reach agreements, and sometimes compromise with them
  - ✓ …

Key points to be recognized

- RA has to and/or need to
  - ✓ Communicate
    - with all the stakeholders
    - for all projects

    depending on different situation in each case.
  - ✓ Recognize gaps between you and stakeholders
  - ✓ Consider the role and responsibility of each stakeholder
  - ✓ Try to reach win-win situation via good communication

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Summary

- Good communication to Win-Win situation:
  - ✓Helps applicants to improve quality and efficiency of the product development and registration process
  - ✓Leads more speedy approval
  - ✓Results in earlier patient access to new products

Practice/Lecture2

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Akiko Ikeda

Practice/ Lecture2 Agenda

Items	time	presenter
Explain practice part 1	10 min	Akiko Ikeda
Group discussion	20 min	All
Result of practice part 1	10 min	All
Explain practice part 2	5min	Akiko Ikeda
Group discussion	25 min	All
Result of practice part 2	5 min	All
Lecture 2	10 min	Akiko Ikeda
Conclusion	5 min	Akiko Ikeda

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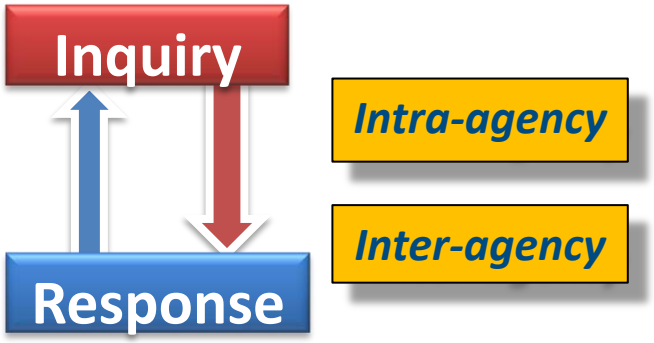
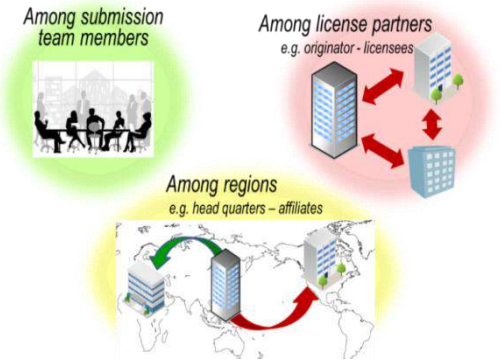
Consultation /Meeting





2. How to prepare before a meeting, inquires from HAs and responses to HAs?
3. How to follow-up after the meeting, inquires from HAs and responses to HAs?

In this session, #2&3 topic above is discussed, especially focusing on miss communication and considering activities on before and after

Meeting/communication with regulatory agencies .

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Effective communication 2

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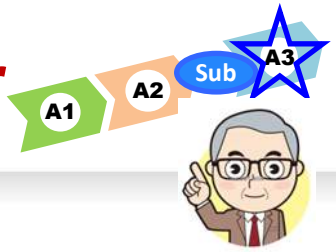
Effective Communication to regulator during review period



- You should confirm **what the regulator wants to know** when you receive **unclear requests**.

  If you prepare the answer sheet without understanding regulator's thought, you may have to receive additional inquiry repeat after repeat. You may waist loss time and resource.

- You should describe clearly **based on evidence data** because of avoid misunderstanding.
- You should explain **including of the background** .

Because

- ✓ Applicants cannot understand what review team discus regarding the inquiry Reviewer also cannot understand what applicant discuss and submit the data.
- ✓ If assumptions are not shared , not lead to a good discussion . If We are able to discuss after understand the problem in terms of the description including the background and concern , the solution found should .

Why miscommunications are occurred?

- ✓ **Risk of verbal communication**
  We often could not grasp the correct information with use verbal communication and hearing from the other persons.

- ✓ **Lack of confirmation**
  Without sufficient verification on the spot , at a later date , when we found the intention of the authorities was different ,
  We waist not only the time, resource , and also we have to do additional working after it.

- ✓ **Issue of translation**
  Example of Package insert, If we mistake the translation of the word, the meaning is different from original message and reviewer sometimes request to add more strict precaution in the PI.

- ✓ We often receive additional inquiries because of **the unclear explanation in the materials.**
  (including case: lead miss-understanding by so long contents in mail)

Team should take notice above factors for avoid miscommunication for approval process.
Good communication between local and global team, between each function is necessary.

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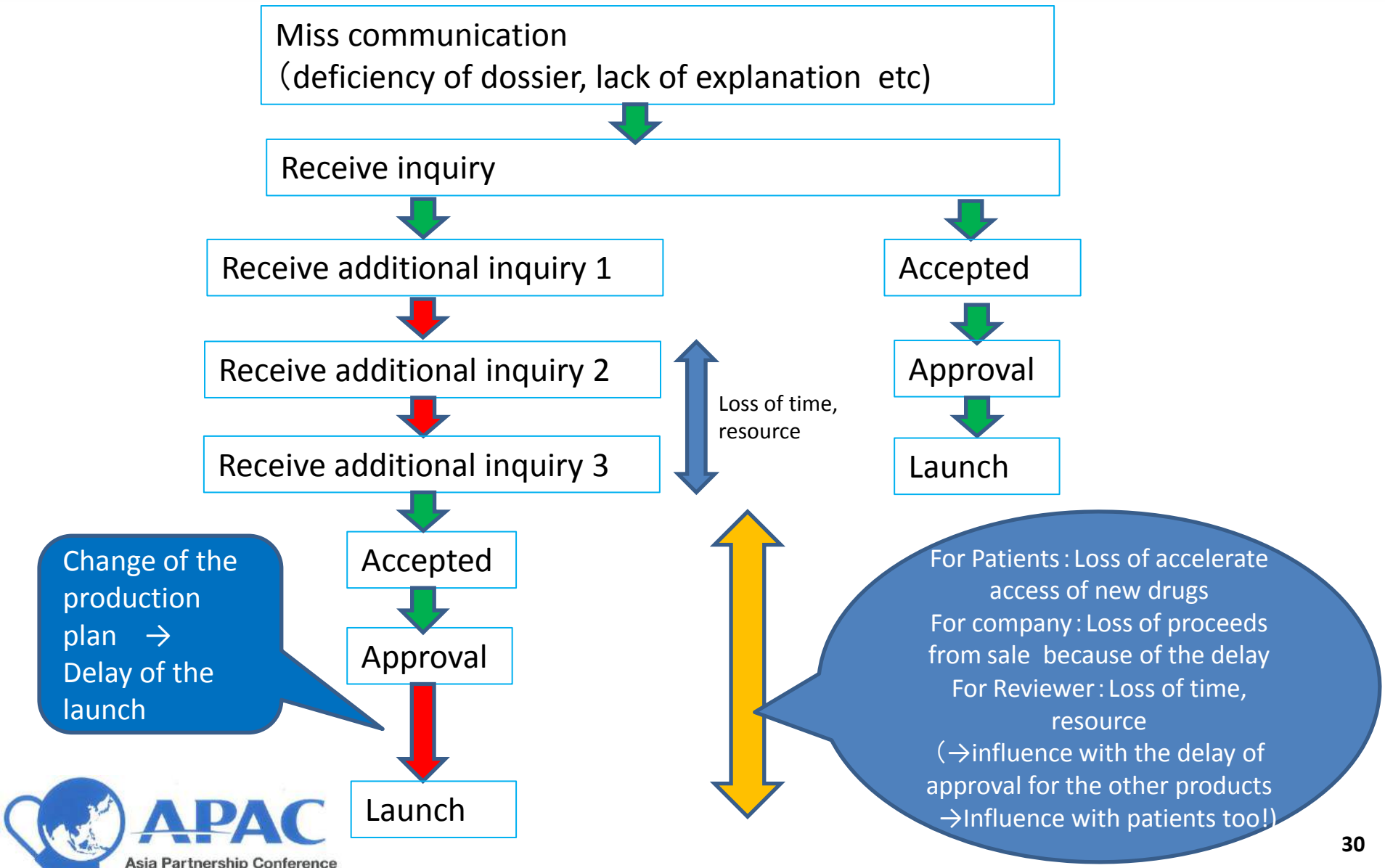
Impact of approval period



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Conclusion

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Effective Communication

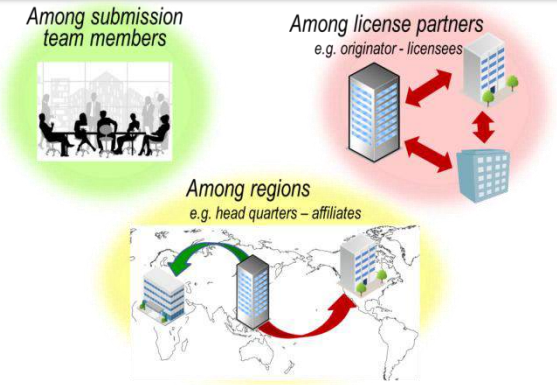
Effective communications will help applicants to improve quality and efficiency of the product development as well as registration process, thereby realize timely approval and earlier patient access to new products. Applicants should foster good communications with the review authorities and those within applicants' organization(s).

◆ *Described TWO types of critical communications for applicants*

1. ***Communications with review authorities***

Consultation /Meeting

2. ***Communications amongst applicants***



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Communication during development

Drug Discovery → Pre-Clinical Development → Phase I → Phase II → Phase III → Application Submission → Review & Approval → Post-Approval

With Health authority

Consultation

Pre-meeting

- Rehearsal for presentation
- F2F meeting

Telephone call

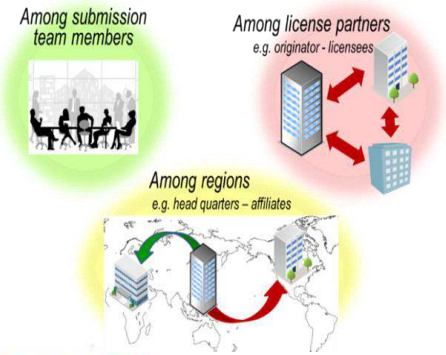
Inquiry

Response

One to One conversation

Within applicants etc…

Meeting/Discussion within many internal stakeholders



Kick off meeting for submission team

- Rehearsal for meeting
- Pre-meeting

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