efpia

European Federation of Pharmaceutical Industries and Associations

Continuous dialogue from product development throughout the product life cycle

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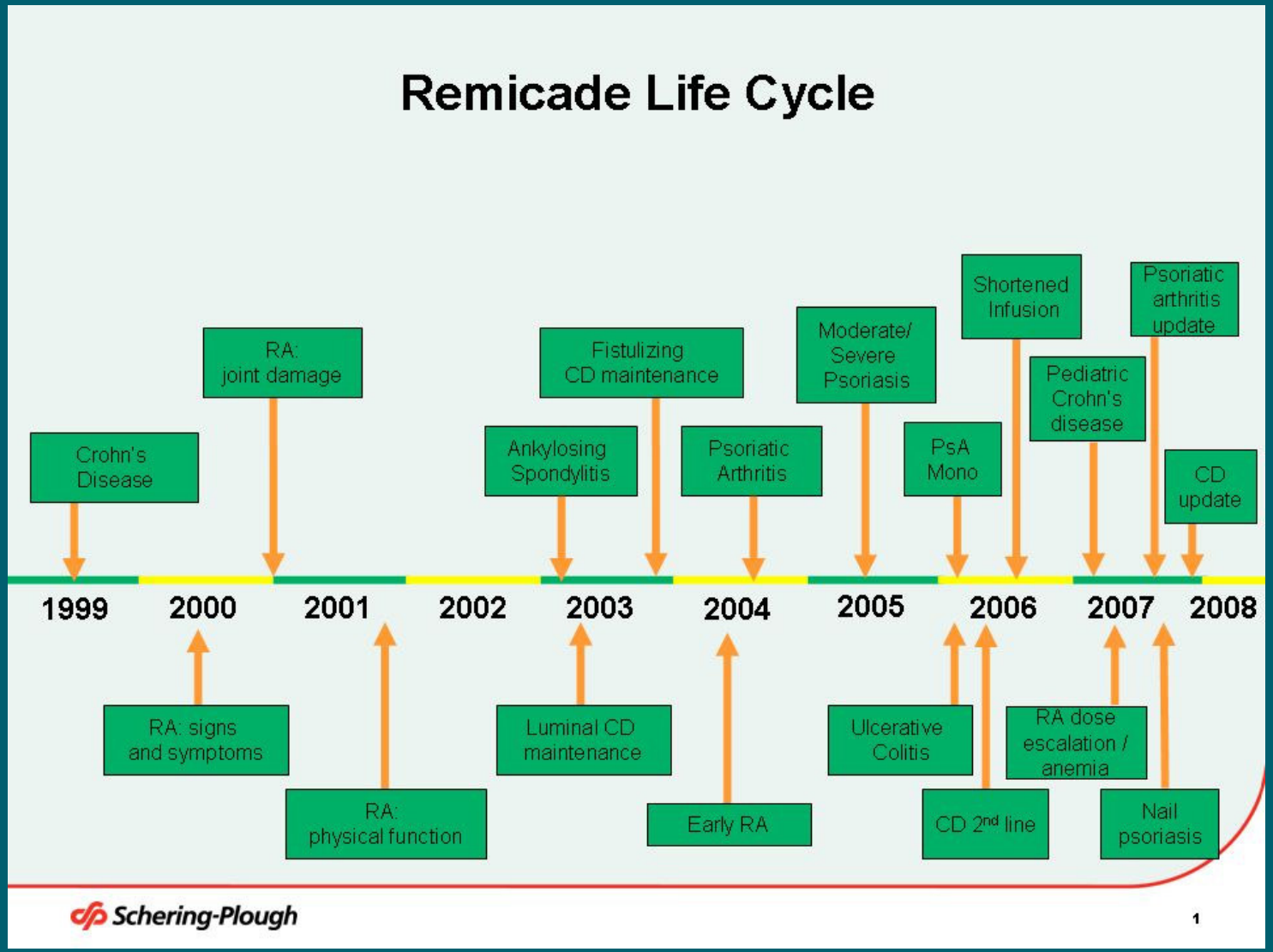
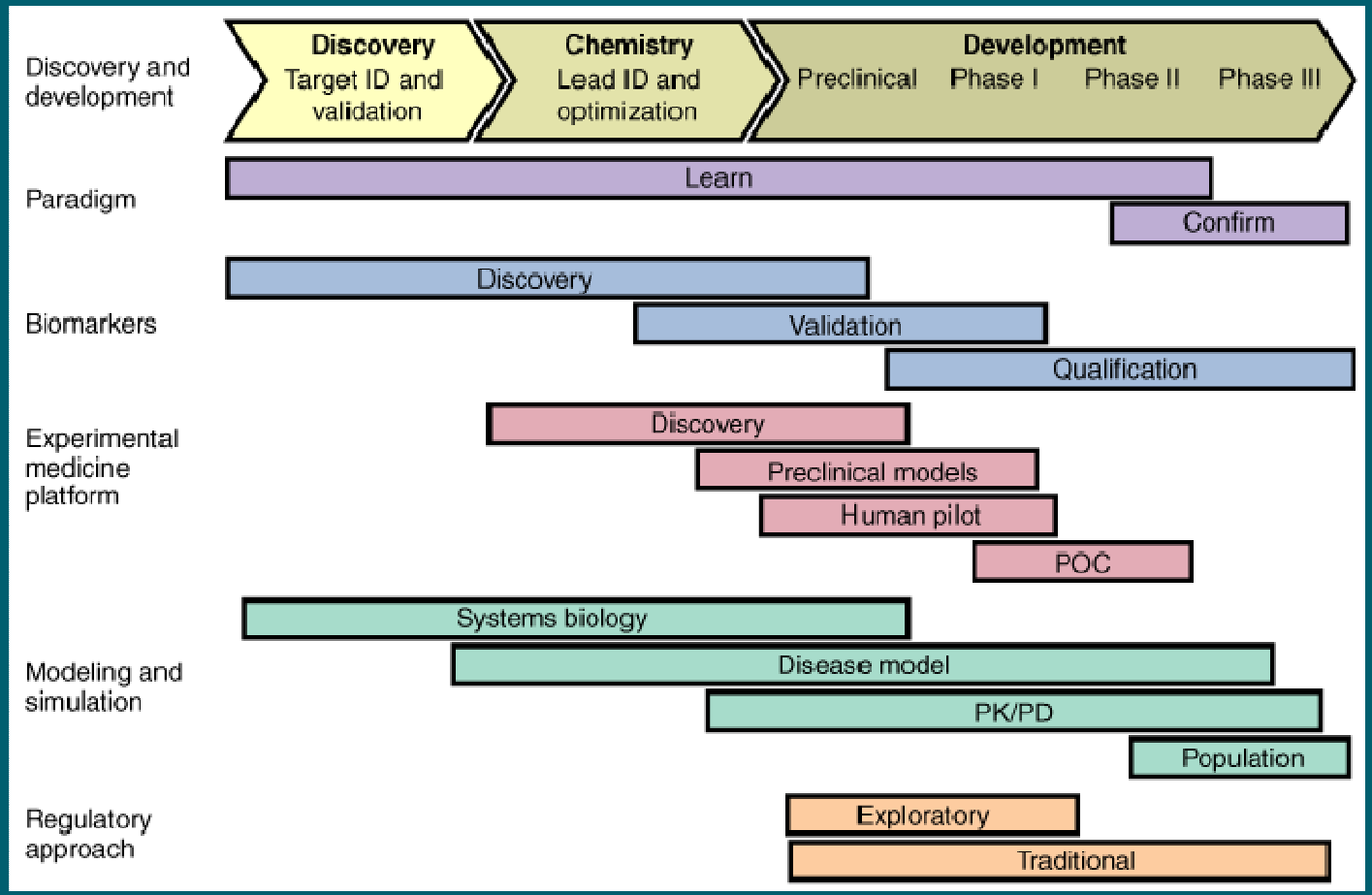
February 24, 2009

Product life cycle is a reality



Innovative strategies in drug development



Wagner JA, Clin Pharmacol Ther 2008;83:199-202

More complex development

- Quality by Design
- Bridging strategies to (first) human exposure
- Use of biomarkers
- Use of innovative methodologies
- Advances in clinical trials:
  - Adaptive designs
  - Use of pharmacogenomics
- etc

EMEA/CHMP-Think-Tank Group

- Better use of scientific advice procedures especially at milestones
- More flexible ways for minor advice and follow-up clarifications
- Less formal and less binding “briefing meetings”
- Peer review of SAs by CHMP members as bridge to rapporteurship

EMEA March 22, 2007

EMEA/CHMP-Think-Tank Group

"…will provide opportunities for a more continuous , easier, long-term dialogue with companies."

EMEA, March 22, 2007: page 13

Rapporteur as link to Science

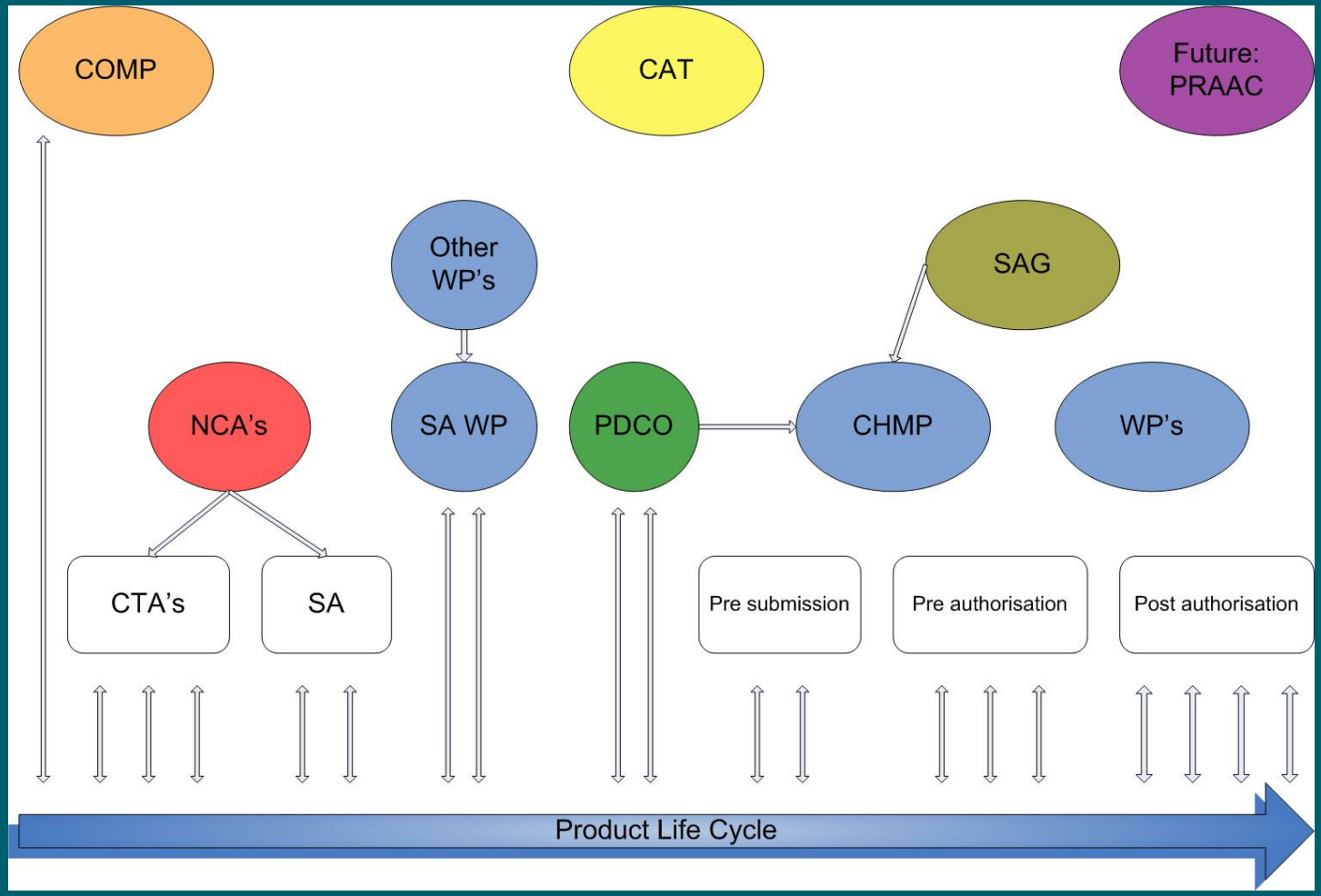
EFPIA proposal:

- At first Scientific Advice Rapporteur (NCA) is selected. During lifecycle he/she (NCA) will remain the lead person
- Access facilitated through Product Team Leader (EMEA)
- For MAA and susequent variations the Co-rapporteur will be appointed
- Peer review by CHMP as usual

More complex regulatory environment

- Legislative framework more detailed
- More detailed guidance documents
- Within EU network many competent authorities
- Within EMEA several scientific committees with overlapping and potentially conflicting responsibilities (e.g. SAWG vs PDCO vs CHMP)

Interactions with EMEA and NCA's



EMEA's increasing complexity: examples

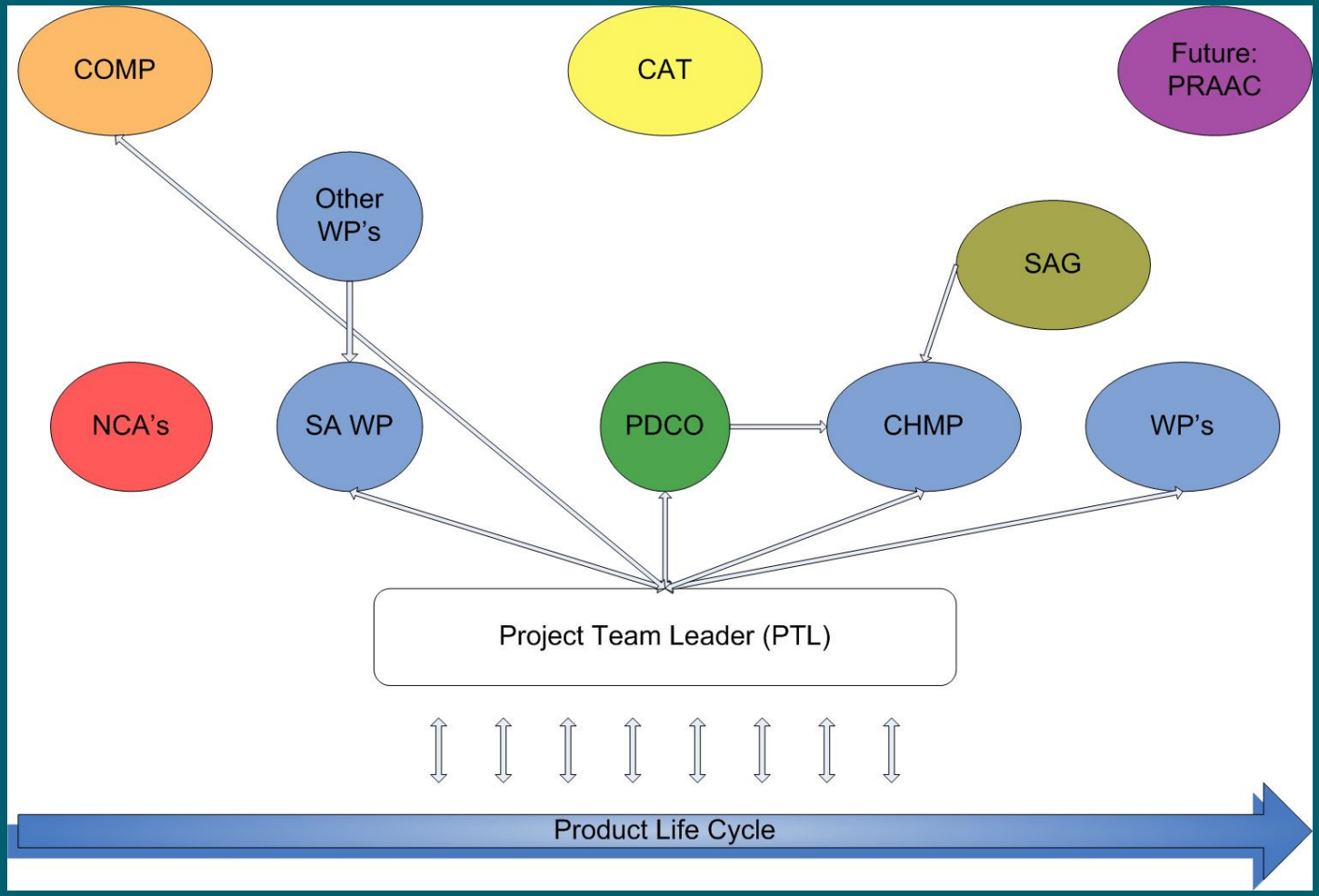
- EMEA Policy on appropriate coordination between the scientific committees of the agency (Oct 31, 2008)
- Procedural advice to CHMP members (Aug 6, 2008)
- General dealings between SAWP Secretariat and working parties, SAGs, committees and patients' organisations (Jan 15, 2009)

EMEA Secretariat: new role ?!

- “shall provide technical, scientific and administrative support for the Committees.”
- “safeguarding the scientific and regulatory quality and consistency of the opinions and recommendations of such Committees.”
- “..the current concept of Product Team Leaders throughout the lifecycle of medicinal products will be further strengthened to allow enhanced coordination during the assessment…”

EMEA Roadmap 2010, March 4, 2005

PTL as the focal point



New role of the PTL

EFPIA proposal:

- “Account manager” during the product life cycle
- Serves as interlocutor to the Scientific Committees
- First point of contact for technical, regulatory and scientific information
- Facilitates access to Rapporteur
- Works closely with the (Co-) Rapporteur especially for scientific issues

Summary

EFPIA supports EMEA's ambitions to implement the proposed measures to enhance a continuous dialogue

In addition and specifically EFPIA proposes:

- PTL as "accountmanager" during the product life cycle
- Early appointment of Rapporteur