Regulatory Strategies in the New European System

6th DGRA Annual Conference

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⇨What is new?

⇨Which news have implications for Regulatory Affairs?

⇨Which news have implications for the entire company?

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What is new?

- ⇨Variations Regulation
- ⇨Common Technical Document
- ⇨Implementation of clinical trials directive
- ⇨New EU Directive on pharmaceutical legislation
- ⇨New Regulation on EMEA and the centralised procedure
- ⇨EU Enlargement

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Two classes of “news”

1. Those, which just need to be followed
   - ⇨ Variations Regulations
2. Those which change procedures, workloads, and timelines (and costs!)
   - ⇨ Common Technical Document
   - ⇨ Implementation of clinical trials directive
   - ⇨ New EU Directive on pharmaceutical legislation
   - ⇨ New Regulation on EMEA and the centralised procedure
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Everything has changed

⇨A good strategy is the only way to survive

⇨Do the strategies need change?

⇨Or do we need to follow them in a more stringent way?

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CTD

- ⇨Developed for global submissions of NME's
- ⇨History: Never more than 50 NME's per year
- ⇨Format for all new submissions incl. variations
- ⇨All "old" dossiers, i.e. those with NtA structure, need to be changed
- ⇨Considerable additional workload (10 – 20 days for every single CMC dossier)

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Implications for regulatory affairs

- ⇨ Additional “non productive” workload needs to be covered
- ⇨ ***All*** old dossiers will have to be brought in line with CTD
- ⇨ Trigger for change: Variations to part II of the dossier
  - ➢ Main issue: communication to all departments which trigger dossier changes: Everything has to be planned with the right lead time for regulatory affairs
  - ➢ Resources need to be defined: internal vs. external

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Implementation of the clinical trials directive

- ⇨Country by country basis
- ⇨We look forward to the discussion tomorrow
- ⇨Issue: Who prepares the IMPD?
  - ➢CMC part (according to CTD): Regulatory affairs
  - ➢Other parts: organised and arranged by those who are familiar with preparing dossiers: Regulatory Affairs

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New pharmaceutical legislation and EU enlargement

- ⇨Company decisions:
  - ➢Choice of “right” registration procedure for NME’s
  - ➢Choice of scientific advice
    - ➢Central vs. local (national) vs. none
  - ➢Choice of name of (new) medicinal product
  - ➢Choice of countries to be part of “first wave”
  - ➢Choice of partnership
    - ➢Co-promotion, co-marketing, marketing without partner

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Strategies

Every item or issue, where the company has a choice, comprises an element of the overall development and submission strategy

Example: Choice of procedure

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Choice of “right” registration procedure for NME’s

⇨Major determining factors:

- Medical school in the different MS in the EU
- Early market entry in one major market vs. immediate licence throughout EU
- Patent and SPC coverage vs. data protection
- Competitive situation (first in class vs. improved new molecule)
- Company representation in the EU MS’s
- Partnering and marketing scenarios

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This is a lot of choices
How should it be done best?

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1. Collection of information

⇨Via scientific advice with national authorities

- ➢National specialties
- ➢Willingness to act as RMS or Rapporteur
- ➢Working atmosphere: Can we do this extremely important thing together?
  - ➢***Both*** parties have to be satisfied

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2. Decision matrix

- ⇨Weighing of different bits of information
  - ➢Objectivity of information
- ⇨List of all relevant items
  - ➢What is more important gets a higher score
    - ➢Examples: Strength of local subsidiary, scientific backing by internal scientists/opinion leaders

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3. Communication

⇨Goal: Transparency of the decision

⇨Information of all stakeholders

⇨Information of and buy in by senior management

⇨All this shall lead to a final plan:

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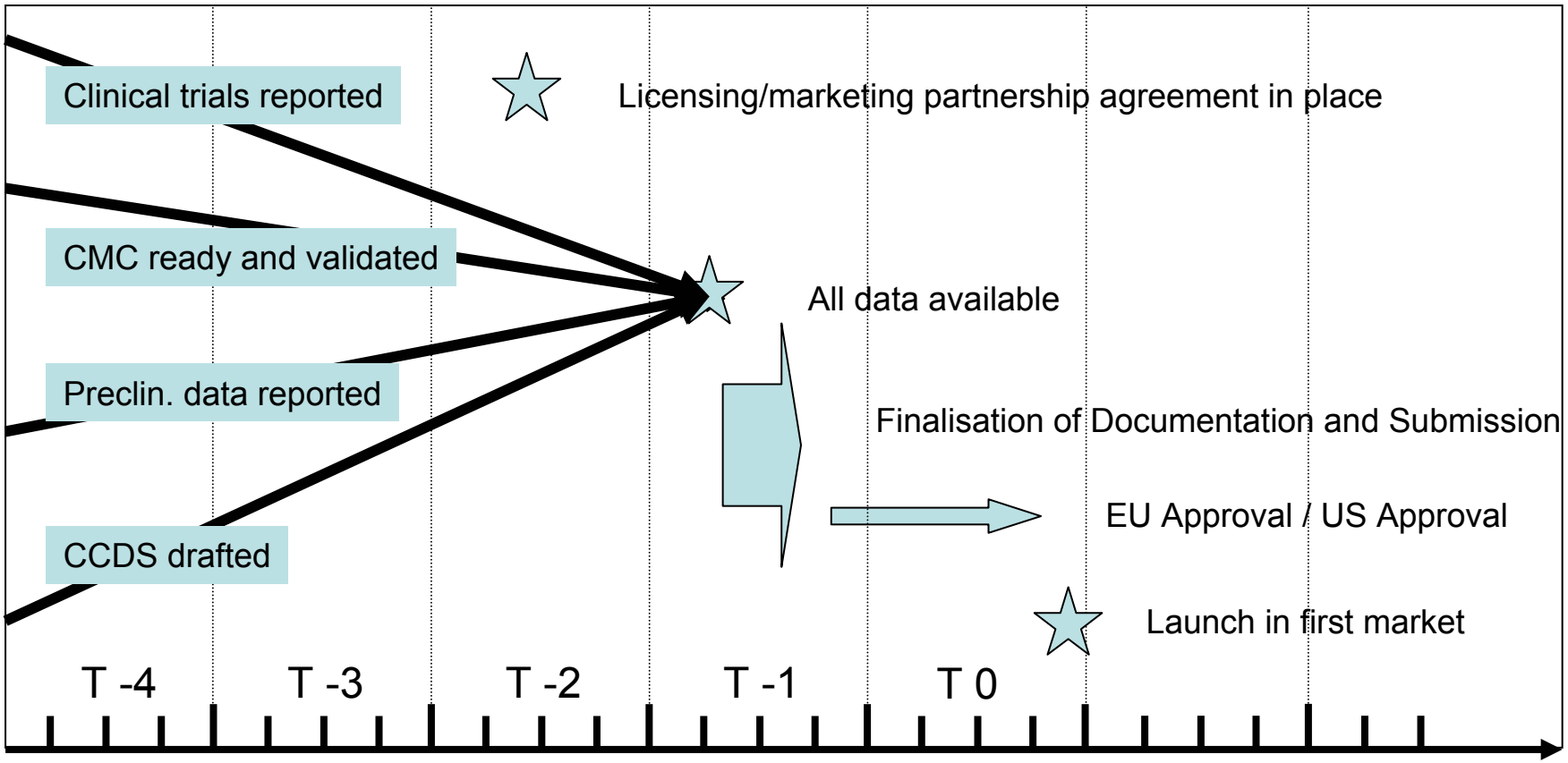
Overall Plan



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What does this all mean for Regulatory Affairs

⇨New tasks:

- ➢IMPD
- ➢CTD and its change
- ➢dealing with 21 instead of 11 sets of labelling
- ➢Working with 27 agencies under the EU umbrella

⇨***More work***

But also…

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New Chances for regulatory affairs

- ⇨Role within the company is increasing
- ⇨Job becomes more demanding
- ⇨Company critical decisions are being based on regulatory know how
- ⇨Every decision has to be based on the question: Is this in line with our knowledge on an enlarged Europe

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Thank You

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