6th DGRA Annual Conference

# FDA - EMEA Interaction Implications for the Pharmaceutical Industry

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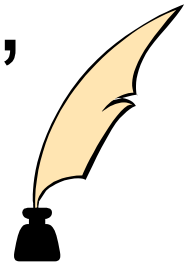
Competetive global environment and high development costs

demand for an

efficient global drug development program appropriately proving safety and efficacy and providing access to all major markets

# Information-Sharing Agreement FDA/EU signed by FDA, EMEA, and EC September 2003



- EU-FDA bilateral meetings since 1989
- PhWG/FDA monthly videoconferences on Pharmaco-vigilance
- Now strengthening communication in step wise approach to include - orphan drug designation
  - inspection reports
  - marketing approvals
  - post-authorisation surveillance information
  - parallel scientific advice

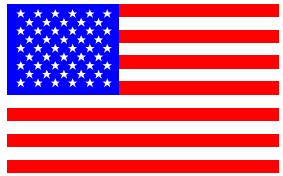
# EMEA perspective

- Confidentiality of non-public information will be protected
- Industry benefit: opportunity for parallel Scientific Advice

  [EMEA Press release Sep 2003]
- More focus on global development is required, but very resource intensive [T.Lönngren at DIA March 2004]
- Parallel SA only when the company is volunteering

  [D.Brasseur at DIA March 2004]
- Company may potentially be involved immediately after conference [M.Toivonen at DIA March 2004]

# FDA perspective



- Share important information about
  - pending approvals
  - post marketing surveillance
  - enforcement actions
- To build understanding and mutual confidence

[FDA Report 2003]

- Joint Advice can occur in a number of ways, including ...a videoconference...with company representatives

[M Lumpkin, RAJ Nov 2003]

- Joint policy development [S.Hirschfeld DIA, March 2004]

# First parallel EMEA-FDA Scientific Advice procedure (pSA) September 2003

- For orphan dug at request of the sponsor
- During Protocol Assistance (PA) after oral hearing in EU
- Prior to EoP 2 meeting at FDA
- Videoconference of EMEA and FDA assessors
- Chaired by M.Toivonen, observer T.Lönngren, M. Lumpkin
- On scientific issues on the proposed development plan
- FDA / CPMP continue to adopt advice independently

# First experience of pSA at EMEA

- High expectations/interest from sponsors
- EMEA already before requested FDA advice from sponsor
- Each agency remains responsible for its own advice

  [M. Papaluca Amati, at CMR Sept 2003]
- Parallel SA provides arena for agency discussion but outcome is not binding for any side

  [T.Lönngren at DIA March 2004]
- Two further requests for parallel SA received
- Points for discussion on preclinical and clinical issues

  [M.Toivonen at DIA March 2004]

# 2003 EMEA survey on Scientific Advice

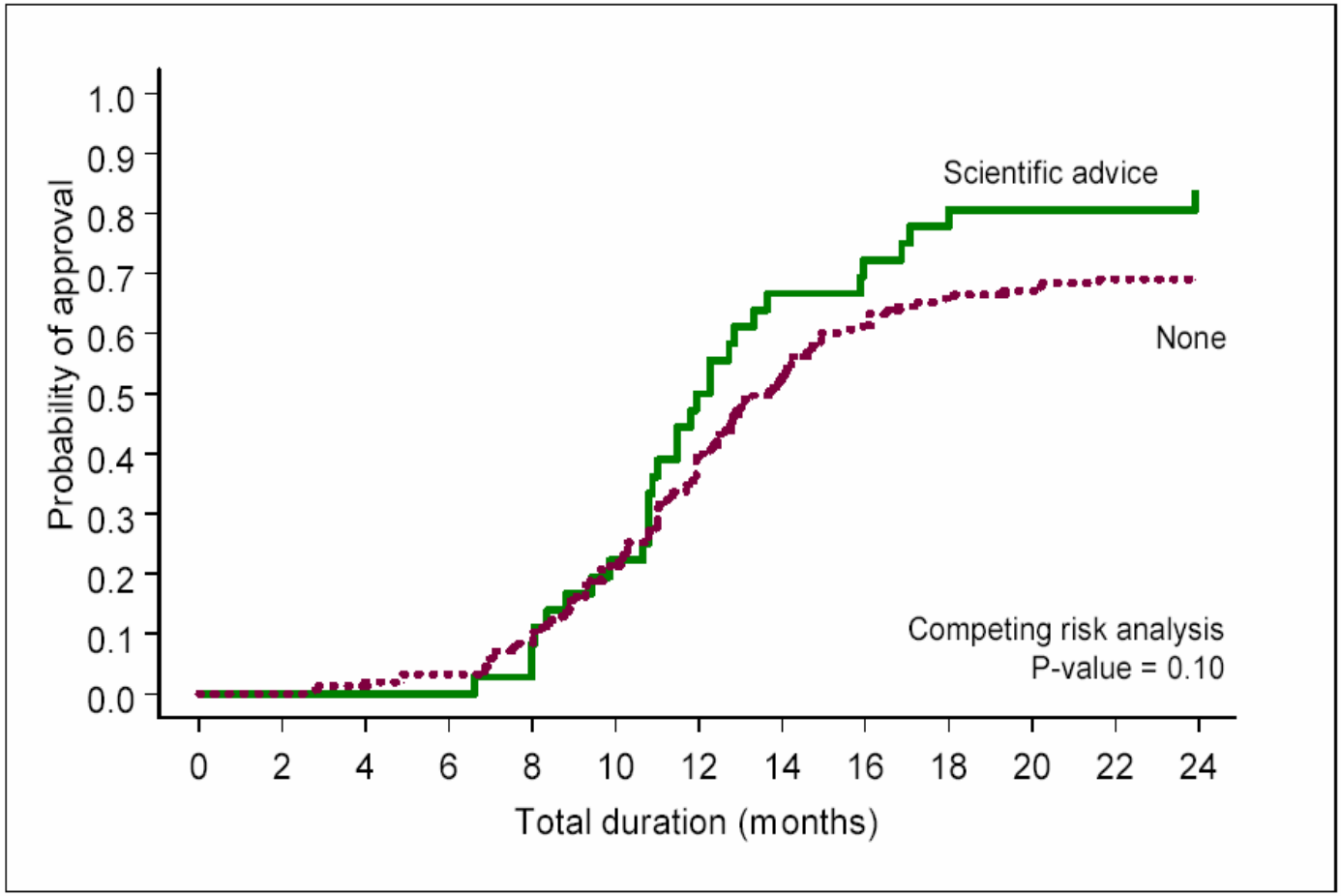
Jan - Sep 2003

n=41 questionnaires, 36 SA and follow up, 6 PA

- 58 % Clinical questions (thereof 56 % Phase III related)
  26 % Preclinical questions
- 12 % found advice very different from the one received from other authorities
- 19% had to devise a completely different development plan after the advice

[Prof M Toivonen, DIA meeting March 2004]

# Impact of Scientific Advice (n=41) on proportion of approval over time




[9th Annual report EMEA activities 2003]



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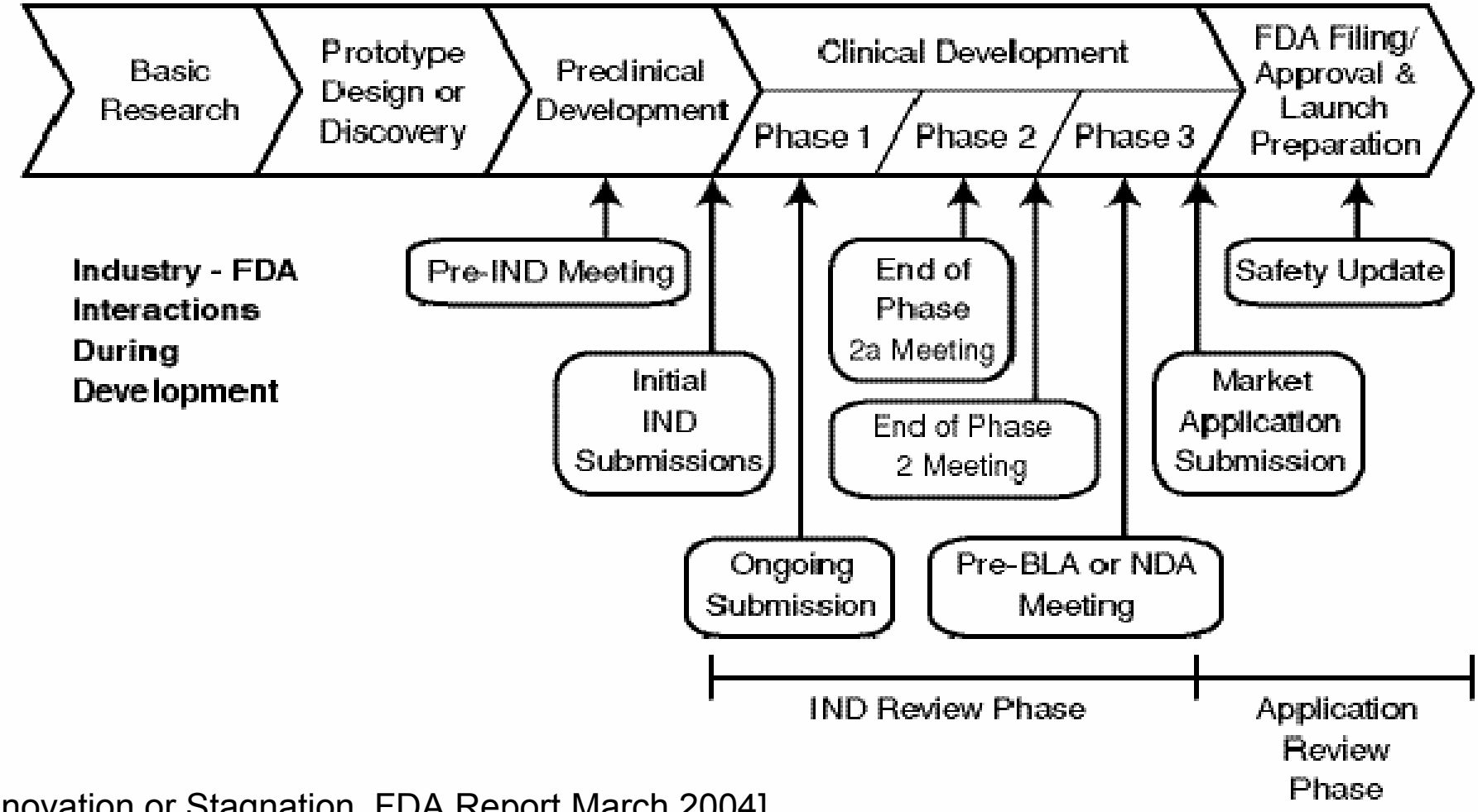
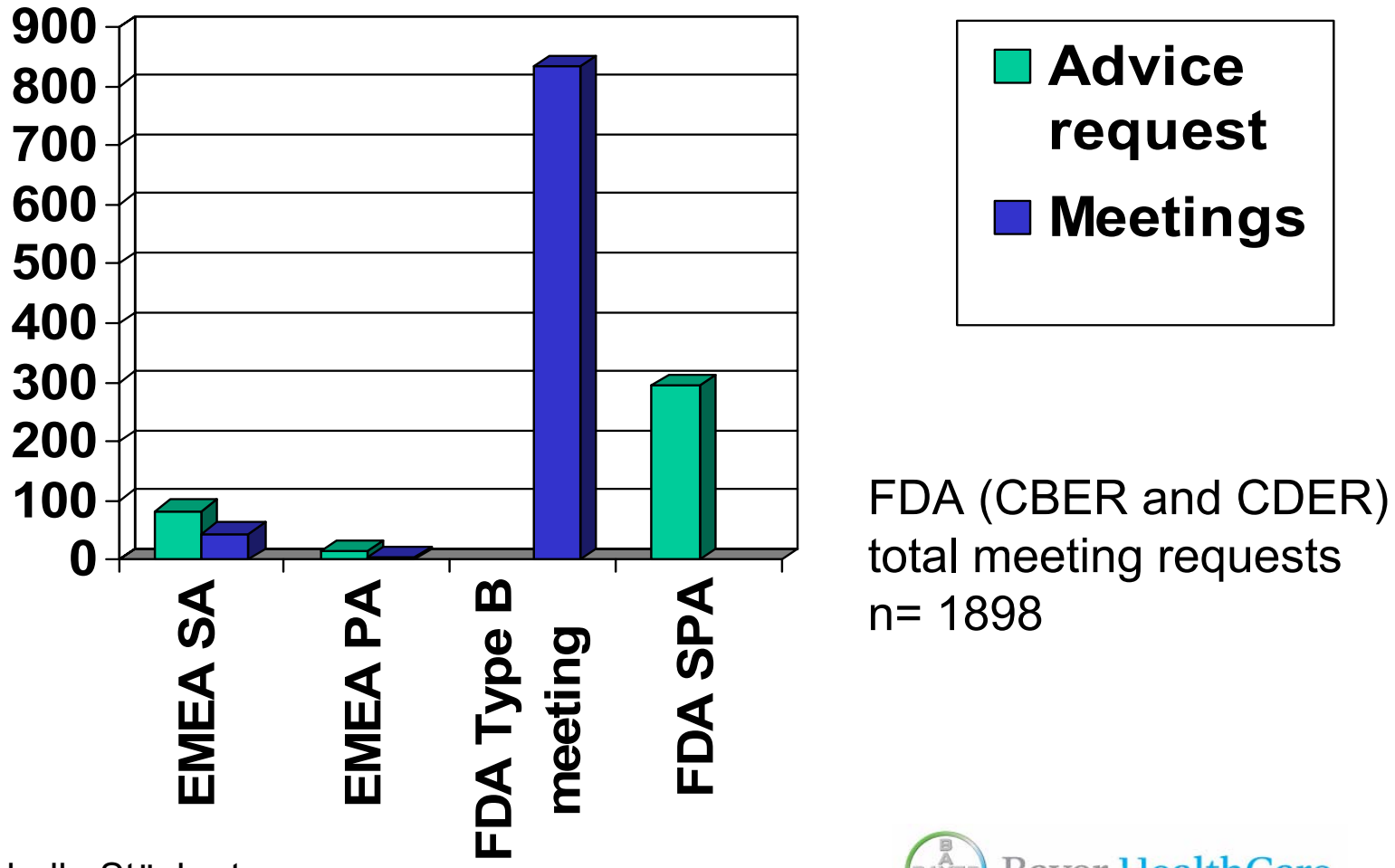
# Industry - FDA interactions during drug development



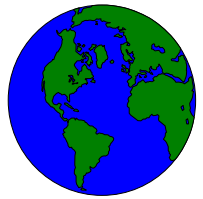

[Innovation or Stagnation, FDA Report March 2004]

# 2003 EMEA SA, PA and US Type B meeting, SPA requests



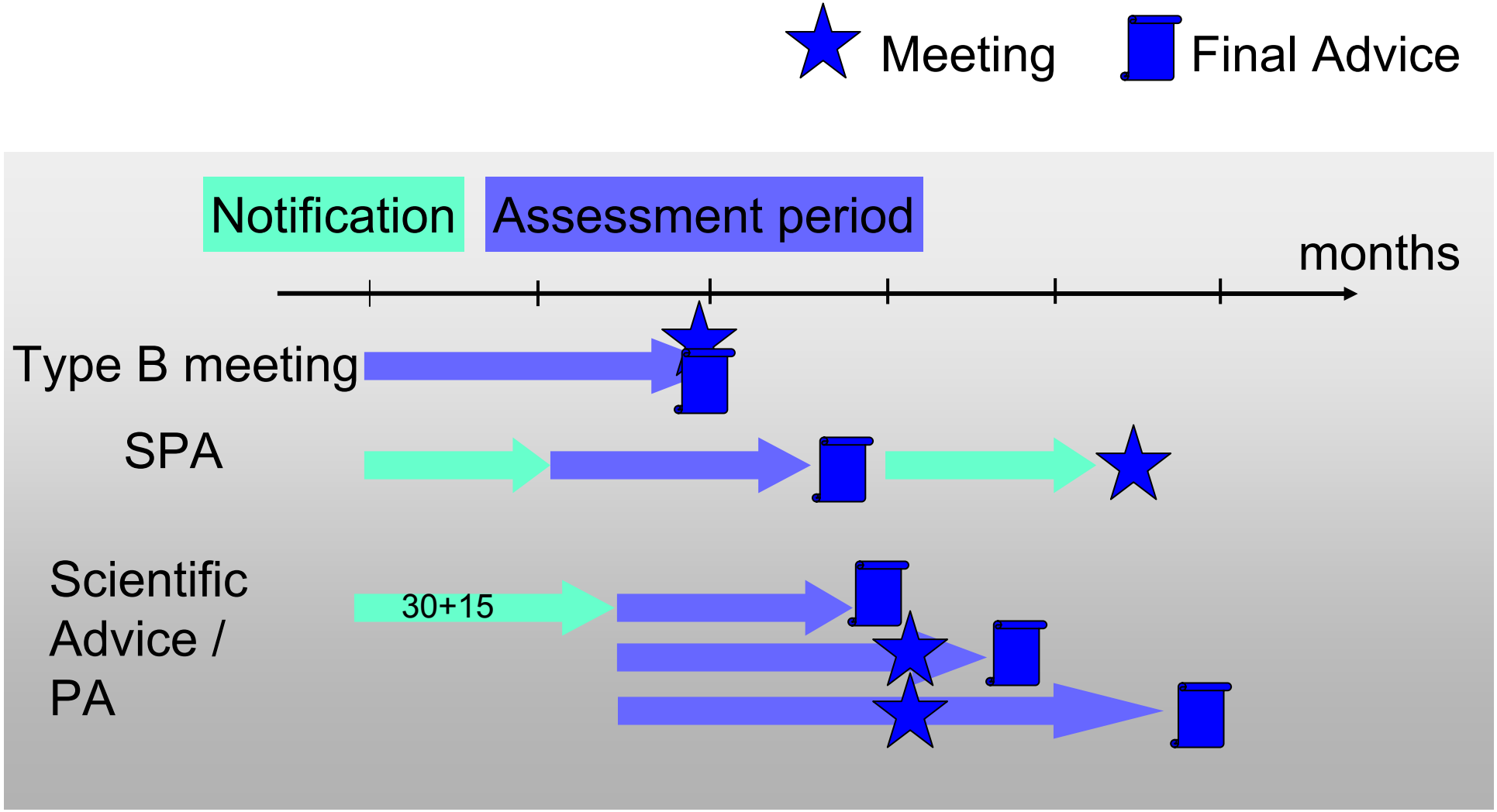

FDA (CBER and CDER) total meeting requests n= 1898

# Industry perspective - Benefits pSA



- Allows for discussion and maximal information exchange on scientific issues
- Fills gaps if no guideline or precedent is available (see also announced shared guideline development)
- Strengthens Regulators guidance/impact during development
- May help to avoid unnecessary study replication in the two regions if agreement can be reached on an appropriate level - efficient global development plan

# Scientific Advice timelines EU and US



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# Parallel Scientific Advice - Timelines

- Meeting co-ordination major challenge for project managers, inform well in advance
- Parallel approach needs exact timing
- Feedback in writing is no option in this case
- Delay by 2 m expected compared to conventional procedure

# Industry perspective - Risks of pSA

- Missing transparency
  - procedure so far not formally described
  - industry not allowed to participate
  - there will be no joint outcome document
- Not really joint but parallel, outcome may differ
- Risk for higher hurdles (group dynamics, differences in therapeutic environment)
- Prolongs overall timelines for authority advice

# When should Industry use pSA?

- For issues that can be solved on scientific level independent of therapeutic environment
- For conflicting EMEA/FDA advices that are major obstacles to further development
- If access to all markets by full program not speed to market is driver of development
- If CPMP and FDA guidelines deviate considerably
- To harmonise comparator treatment
- To benefit from special expertise of one authority

# What Industry would really need

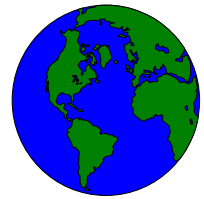
Transparency ! -EMEA SA: Inform industry on preliminary advice to allow for pSA within running procedure
-Industry participation in meetings

Flexibility ! - If deviations are seen in seperate advice, an uncompli-cated quick joint follow up procedure is required (4 w!)
- Shorten SA procedure, allow for ad hoc meetings
- Try to reach compromises that support globalisation

Simplify ! Develop effective and simple structures for meetings of (too many) stakeholders involved, i.e. with Drug Device combinations, several indications, pediatric and orphan drugs

# FDA/EMEA co-operation - Good News

- Possibility for interaction facilitates global development
- SAWG, national authorities interested in FDA position



# ...Not yet so Good News

- Conflict resolution ?
- Sponsor involvement
- Increased FDA/EMEA information exchange needs clear procedures (no preliminary/incomplete information share)
- Guidelines to be developed for all areas
- FDA not yet asking for CPMP position
- What is the impact on ICH ?