APEC Preliminary Workshop: Review of Drug Development in Clinical Trials

Session 11 – Industry Perspective
Data Safety Monitoring Boards and Product Life Cycle

Susan D‘Amico
Vice President and Global Head
Clinical Quality Assurance

© 2008 Novartis
Disclaimer

The information within this presentation is based on the presenter’s expertise and experience, and represents the views of the presenter for the purposes of a training workshop.
Data Safety Monitoring Boards

Industry Perspective
Data Safety Monitoring Boards (DSMB)

*An independent committee established specifically to monitor data throughout the duration of a study to assess if continuation of study is appropriate scientifically and ethically.*

Situations where a DSMB should be considered:

- Trials that are long term or have large patient exposure.
- Trials that involve mortality and serious morbidity.
- On-going monitoring of emerging safety issues in a program.
- Trials that might be stopped early due to overwhelming efficacy or lack of effectiveness (futility).
- Scientific needs—information may be needed for some decisions for go-no go decisions, study trial design, or perhaps planning a future trial.
- Adaptive design—where pre-planned adaptations will be considered based on interim data as part of an adaptive design strategy.
- Health authority requests.
Product Life Cycle
Novartis Industry Perspective
Life Cycle Management (LCM) is the process of optimizing the value of a molecule over its whole life cycle, within the context of the overall Novartis product and project portfolio.
Why is LCM important?

Successfully developing and commercializing new pharmaceuticals is becoming more challenging, for several reasons:

- Lower R+D productivity (less new molecules; higher development costs per molecule)
- Impact of patent expiries of major products and more aggressive generic competition
- Downward pressure on prices
- Growing safety concerns
- Increasing promotional spend necessary to fund new ways to reach customers and consumers
- It is therefore more important than ever that we optimize the value of our existing products over their whole life cycle. This means striking the right balance between maximising existing brand assets and creating new ones.
Thank You

for your attention!

Questions?