Safeguarding public health

M&S good practices and next steps

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M&S good practices

No intention to lecture this audience on ‘good practice’

M&S good practices

Different standards for different exercises (L,M,H)
Standard should be high!

- Assumptions (not only mathematical)
- Model building rationale
- Model testing
- Inference
- Sensitivity analyses / Challenge assumptions
- Reporting

Detail of regulatory response might be vary according to impact

M&S good practices

Assumptions
- Formulating, challenging

Avoiding selection bias

Avoiding ‘conflict of interest’ bias

M&S good practices

Communication
- To whom?

Adding objectivity to inform a better subjective decision

Based on sound scientific understanding
- How often is this possible?

M&S good practices

Pre-specification
- Before analysis
- Before data?
- Contradicts modelling?

Guidance
- Adequacy of pop PK reporting for all M&S?
- Possible?
- Helpful?

M&S good practices

Building experience

Building trust

Safety and efficacy

Changes in regulatory assessment process (“scrutiny”), but not changes in regulatory standards

Next steps

Clarify options for discussion

- EMA / CHMP Scientific Advice
  - Product specific
  - Broad scope
  - Qualification process
  - Parallel FDA
  - Parallel HTA
- EMA / Innovation Task Force meetings
- National SA (Product specific, broad scope, parallel HTA)

Next steps

Advice on advice

- Pre-submission meetings with EMA
- Ask the right questions
- Provide the right background
- Ask clarification / follow-up

Next steps

Workshop report
Discussion at EMA / CHMP
What to do?

- Guidance?
- Working Party?
- Collaborations – academia, other RA