Optimal Design SWOT Analysis – Pharmaceutical perspective

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Abstract

Optimal Design has much to offer the Pharmaceutical Industry, especially under the current environment which is driving for efficiency. This efficiency is also being demanded by the drug regulators (FDA White Paper on 'Innovation & Stagnation'). As such, this should be a golden era for Optimal Design. **From Pfizer's perspective, the interest is good but the application is surprisingly limited. By means of a SWOT analysis, aim of this presentation is to generate discussion on why and what can be done to increase its use.**

Setting

- Pfizer perspective
- Aim to generate discussion, learn and progress
  - Plan for the future

Strengths, Weaknesses, Opportunities & Threats (SWOT)

Strengths

- Its efficient, the idea is an 'easy sell'
- Theory mostly done for FE models
- Can be applied to ME models
- Solution can be checked
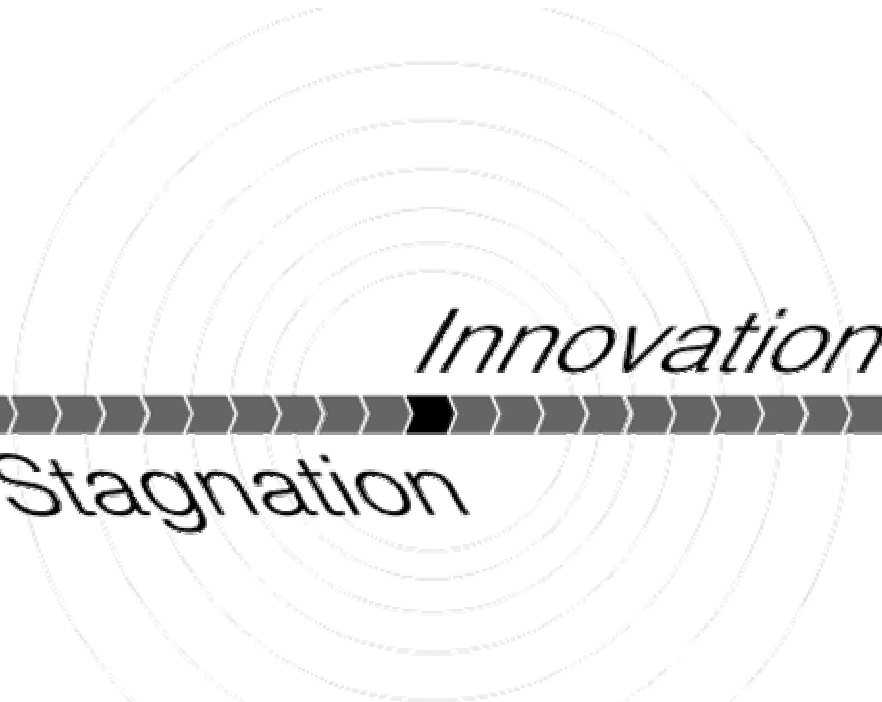- Can reflect uncertainty in current knowledge

Weaknesses

- **APPLICATION**
  - Tools freely available (e.g. ADAPT, PFIM, OPTDES, POPT etc.), why doesn't industry use it more?
- Notation looks complicated, nomenclature confusing
- No General Equivalence Theorem for ME
- Need to incorporate constraints
- Assumptions
- Limited industry expertise & leadership

Opportunities

- Current environment (FDA→ECTD); push for quantitative methods (M&S)
  - Combined with OTD – dynamite

Ted Grasela,
Cognigen

Innovation

Stagnation

**Challenge and Opportunity
on the Critical Path
to New Medical
Products**

The Full-Employment Act for PK/PD Scientists

FDA

U.S. Department of Health and Human Services

Opportunities

- Current environment (FDA→ECTD); push for quantitative methods (M&S)
  - Combined with OTD – dynamite
- Lots of work out there:
  - Not just clinical development (big ticket)
  - Pre-clinical (experimental control)
  - Pharm. Sci & Manufacturing
- Applied problem solving
- Money/funding available

Threats

- Resistance/scepticism
  - Lack of understanding/awareness & training/resource
- Industry short sightedness

Discussion