EFSPi Leaders Meeting 2019 Future skill sets for drug development

**Portfolio strategy**
- Portfolio management
- Decision making support (p[success])
- Strategic thinking

**Product Global Life cycle**
- Discovery to market access
- Model-informed development plan

**Innovative and complex trial designs**
- Adaptive, Bayesian, multi-phase
- Biomarkers
- Modelling & simulation

**Real World Evidence**
- PharmacoEpi
- Observational research
- Pre and post launch
- Pragmatic trials

**Digital Health**
- Wearables, apps, devices
- Electronic health records
- Connected networks

**Data Science**
- AI/machine learning
  - Data mining
  - Prediction tools
  - Data visualisation
  - Advanced analytics

**Data integrity**
- Centralised statistical monitoring
- Quality tolerance limits

**Real World Evidence**
- Data privacy
- Disclosure
- Data anonymisation
- Risk methodology

**HTA**
- Health economics
- Comparative effectiveness
- Evidence synthesis
- Indirect comparisons / NMA

**Interactions with Regulators & HTA agencies**
- Early science advice
- ICH, FDA, EMA, PMDA, CDE guidelines
- Meeting the needs of all stakeholders

**Organisational strategy**
- Roles and structure
- Core capabilities
- Shared resource models
- Outsourcing
- Building expertise

**Internal and External Collaborations**
- Communication skills
- Leadership skills
- Cross-functional partnerships
- Influencing skills