

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

Data Transparency

- 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