NXT Generation Statistician

Goals

- Ensure new graduates have or quickly gain, exposure and understanding of:
  - full drug development process
  - the various expanding areas of statistical influence:
    - biomarkers, non-clinical, pharmaco-epidemiology, clinical, Benefit/Risk

Strategy

- EFSPI to consider possibility of "summer school"
  - similar to PSI ITIT course, but run intensively over a two week period, or
  - extend PSI course to EU, but include goal 2 above
- Universities to better train/prepare graduates into drug developer statisticians
  - Idea: EFSPI to support "Pharmaceutical statistics" lecture series in universities

Follow-Up

- EFSPI: consider representation on funding bodies for Stats MSc/PhD's
  - eg., EPSRC council in UK
  - to provide industry perspective on what elements of courses are most useful to Pharma
- EFSPI: contact universities to initiate discussion on their opinions of how to achieve goals

EU differentiators

Goals

- Maintaining collective expertise in EU
  - regulators, academics, payer organizations
- Promoting advantages of EU
  - focus on strategic value of EU
  - competence in working with partners
  - cultural diversity, convenient time zone
- Strong link between Regulators, Industry and cooperative groups

Strategy

- Organize links to payer organizations
- Maintain link to regulators and academics (e.g., NICE)
- Reach out to and align with other professional organizations
- Generate joint meetings

Follow-Up

- Monitor establishment of links, organization of meetings

Areas for success now

Goals

- Involved in B-R assessments (also to fulfil requirements)
- Become expert and key-player in the pertinent data methodology & communication on B/R within our companies

Strategy

- Understand regulatory requirements (and other stakeholders)
- Think in framework (rather than techniques)
- Communicate EMA Pilots (to statisticians) within company
- Start/initiate B-R analyses on your compound
- Encourage statisticians to focus on communication (graphical presentation/ sensitivity)

Follow-Up

- Ask SIG to prepare slide deck on EMA pilots to help statisticians to communicate by end 2012
- Develop experts in your companies (say at least 2) by Q2 2013
- More events/workshops on B/R within Europe 2012/2013
  - Proposed action for EFSPI: repeat B/R workshop (held in June 2012)

Change Management

Goals

1. Identify skill sets of leaders & individuals
    - *soft skills required to drive innovation*
    - leaders skilled to champion change
2. Increase awareness, get sense of urgency
3. Nature/direction of change
    - *vision in x years (specialize/model)*
    - *Identify stakeholders*
4. Support model
    1. How do we help individuals to change?
    2. Where to go for support?
    3. differentiating between companies (big/small/CRO)

Change Management

Strategy

1. Seek external advice & benchmarking against others
2. develop support "package" to leadership
   - leverage company expertise
   - pilot and plan actions in companies
   - sharing "best practices" across
3. Develop vision by iterating "an approximate answer"
   1. at meetings
   2. in communications
   3. with feedback from stakeholders
   4. and (re-)iterate
4. Companies to lead this (plans and actions):
   1. *training in (leadership in) Change Management*
   2. *Sharing "best practices"*
   3. *Communicate (two way self-enforcing: feedback and awareness)*

Change Management

Follow-Up

Within 1 year:

- set up Working Group (end July 2012):
  - to define vision
  - perform benchmarking
  - gap analysis

- Communication
  - Internal, external

In 2-3 years:

- develop, pilot, share "support package"
- develop role/leader descriptions
- year 2 "design"
- year 3 "implementation"