Session 3 Summary

Group 1: How are we leading statistics groups?

- What makes us become great leaders?
- How we develop as modern leaders?
- 1. Develop and owns a vision that teams can align behind, understanding environment and mission, positioning statisticians as quantitative drug developers, and can translate that vision to a concrete action plan.
- A great leader has grounded authenticity and magnetism that provides purpose, meaning and direction. Encourage people on the achievable.
- Takes ownership of change management and charting the course. Creates opportunity in times of change, using authenticity, magnetism, and role-modelling listening to diverse internal and external stakeholders.

Group 1: Actions for EFSPI Leaders

- Develop our curiosity, challenge ourselves. Be an active listener who steers team members to achieving the team objective.
- Develop resilience, courage, be deliberate about communication strategies
- Develop presence and self-awareness.
- Seeking cross-functional feedback.
- Consider creating a weekly/bi-weekly calendar block for leadership development/reflection → Find a way to create your own accountability/space to develop yourself as a leader.

Group 1: Actions for EFSPI Council

- What are career progression norms across companies (may be out of our group's scope)
- How we develop our leadership skills as topic for next meeting
- Use part of our EFSPI leaders forum to practice storytelling on our journeys

 share our success and failures in our leadership journeys. Share our
 experience and what we would have done differently, what others can
 suggest we might do differently.
- Start a leadership bookclub read a leadership book periodically and discuss the book. Share our learnings from it, create a blog post from that on what statistical leaders can take away from that.
- Provide adequate supplies of good quality caffeine.

Group 2: How are we managing statistics groups?

- What is changing? What will be needed in the future?
- Pool of people we are managing is becoming different
 - More technically oriented, more needs to teach strategy and design
 - Desire to use different programming languages
 - More applicants without MSc in statistics (gaps/potentials)
 - Different training requirements for new joiners
 - Staff becomes more vocal about their needs, well-being and mental health
 - Neurodiversity training (manage and support special needs)
- Pandemic → Homework (flexible workforce)
 - Need to do more intentionally attractive actions to keep staff
 - Budget constraints/green agenda (less travel) but good technical communication
 - Job can be done from home
 - not forcing staff to the office clarify benefits of coming together –
 e.g. visibility, being part of the team, networking, decision making
 - Strengthen the communication skills for different working styles

Group 2: How are we managing statistics groups?

- What is changing? What will be needed in the future?
 - Highly qualified statisticians (consultants) not available for the needs
 - War on talents across the industry / other industries?
 - Hire and train "not fully" qualified statisticians
 - Diversity of personalities of statisticians use the skill set that is available
 - Compound strategy statistics
 - Methodology statistics
 - Operational statistical analysts
 - Statistical leaders
 - Leave technical/ operational tasks to data scientists, statistical programmers or junior statisticians?

Group 2: Actions for EFSPI Leaders

- Share experience to understand industry trends
- Keep learning from each other
- Not get hung up on the labels (Statistician/Data Scientists/etc.)

Group 2: Actions for EFSPI Council

- What is an "appropriate qualification" for a statistician?
 - Needs update of existing recommendation
 - ICH E9 / MHRA grey guide requires "well trained" statisticians
 - "Appropriately qualified" if no MSc Statistics?
 - Balancing the elements of "Education/Experience/Training"
- Training offer "Leading an analytical workforce"

Group 3: How are statistics groups evolving?

- What are key accountabilities?
- Where groups sit in an organization and levels of seniority?
- Evolving scenarios for around next 5 years period
- Big change because several new roles (data scientist, bioinformatics,...)
- Moving activities from statistician to stat programmers
- Specialised groups to be established (in addition to indication area groups specialised groups for genomics, HTA, RWE, medical affairs..)
- Therapeutic area focused statisticians (adviser), product owners (clinical team members), methodology group (simulation, modelling,..)
- Project level statisticians specialised groups support (RWE, HTA,...)
- Program management role working closely with other stakeholders (DM, PROG,...)
- MedDRA coding
- Summary:
 - project/therapy area roles, scientific specialised roles, program management roles
 - Evolving role of statistician vs role of data scientist vs role of bioinformatician,...

Group 3: How are statistics groups evolving?

- What are key accountabilities?
- Where groups sit in an organization and levels of seniority?
- Accountabilities
 - · Quality, bigger imapct in the future
 - Decision making (e.g. GO/NO GO decisions, definition of biomarkers, decisions based on the probability of success)
 - New role => Data generation lead, Evidence lead (e.g. data driven evaluation of unmet needs, strategic contribution to clin development plan, estimation probability of success)
 - Upscale and educate current and new employees
- Level of seniority
 - Improve empowerment without role of manager, program/project based empowerment
 - Persons in the role of the manager have be often high level scientific, technical background/skills e.g statistics
- Hierarchy / number of organisation levels
 - Tendency to less levels more flatt organisation ?

Group 4: What new roles are emerging?

- How are they different?
- How are we proactively creating new opportunities?
- Ability to deal with complex statistical methods because of very complex data sources and structures
 (external and aggregated data, RWE, HTA, digital endpoints, wearables, safety, signal detection, DCTs,
 operations etc) & AI, role in integrating data, new methodologies, optimality considerations, coordination
 and investment decisions
- Platform trials, more efficient approaches, data visualizations, etc
- Strengthen our ability to interpret results (limitations, regulatory value, multiplicity, consistency of endpoints etc). Concrete implementation suggestions, how to make it visible? Examples: Head of Stat/Biometrics is consulted by senior management, shared release of TLR with clinicians, HAs recommending inclusions of stat methods
- Emerging, strategic Drug Developer roles (not 'study statistician' only), work at portfolio level, calculate pOS at program, benefit risk assessments etc. New opportunities
- Lead Exploratory efforts at all stages, beyond Late Development, including Business Development and L&A
- Share success stories and examples, new roles specializing in the above, job titles to match (ex: statistical program leader, methodology and innovation leader) to reshape the way the department operates and communicate accordingly. Benchmark roles in industry, shift resources within budget
- Enhance entrepreneurial skills, develop vision to move forward, develop soft skills and business awareness

Group 4: Actions for EFSPI Leaders

- Share information and good case studies across industry, in a non-competitive fashion
- Stat Leaders meetings and other opportunities?
- Guide our people and help them to go through the changes
- Update structures org charts, roles and job descriptions and share them within EFSPI
- Communicate up accordingly, ex: 3-y roadmap, vision for departments, etc
- EFSPI position paper!!!
- Create and develop metrics, like PWC, define new benchmarks

Group 4: Actions for EFSPI Council

- Support EFSPI position paper
- Endorse/ promote other actions for sharing information on structures and roles across companies
- Keep this topic as a relevant one for regular updates at Council
- Remain open to welcome different areas of interests and disciplines
- Monitor innovation from other sources outside of pharma