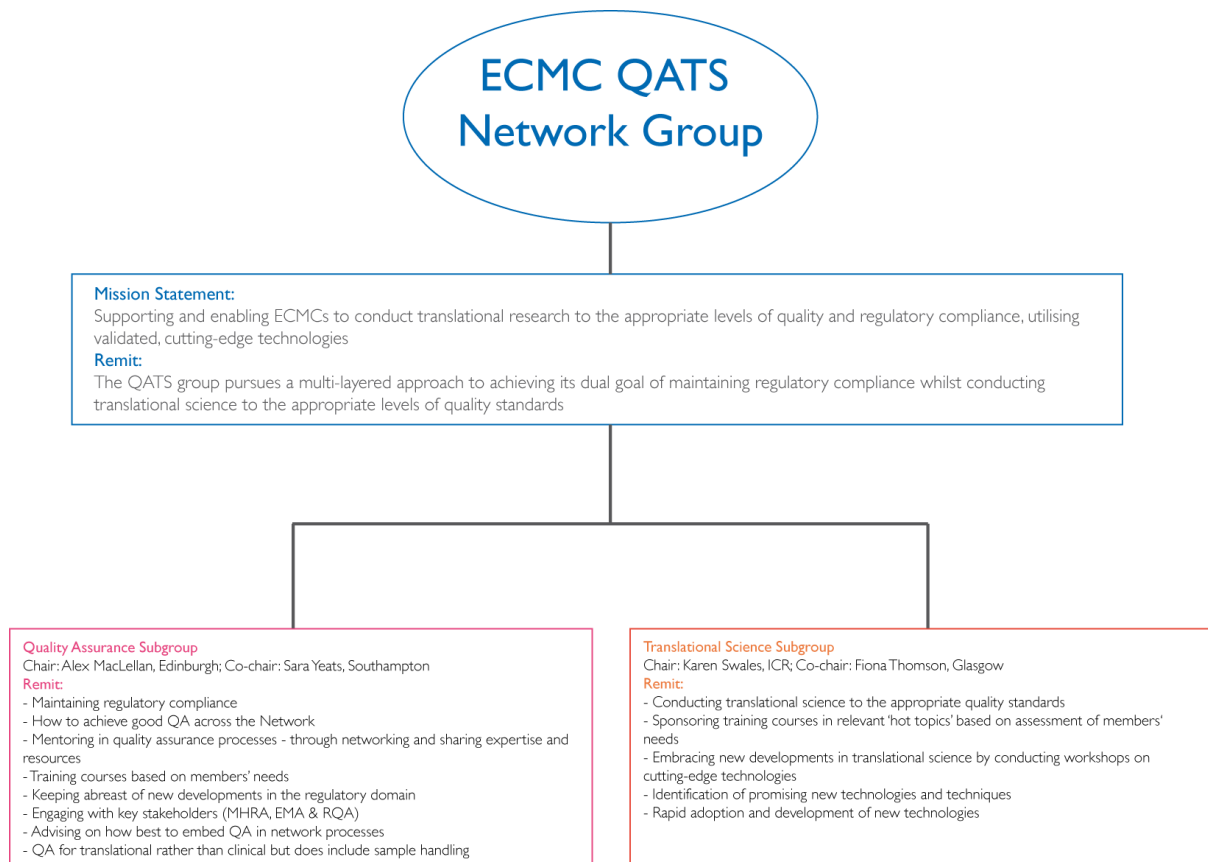


ECMC Quality Assurance and Translational Science (QATS) Network Group Next steps



Mission Statement

Supporting and enabling ECMCs to conduct translational research to the appropriate levels of quality and regulatory compliance, utilising validated, cutting-edge technologies *[add about networking/communications; streamlining; unifying; efficiency; quality]*

Remit

The QATS group pursues a multi-layered approach to achieving its dual goal of maintaining regulatory compliance whilst conducting translational science to the appropriate quality standards.

Quality Assurance Subgroup

Chair: Alex MacLellan, Edinburgh

Co-chair: Sara Yeats, Southampton

Remit

- Maintaining regulatory compliance
- How to achieve good QA across the Network
- Mentoring in quality assurance processes – through networking and sharing expertise and resources
- Training courses based on members' needs
- Keeping abreast of new developments in the regulatory domain
- Engaging with key stakeholders (MHRA, EMA & RQA)
- Advising on how best to embed QA in network processes
- QA for translational rather than clinical but does include sample handling

Objectives

- **Protocol development** – work with the ECMC Secretariat and Clinical Studies Groups (CSGs) <http://csg.ncri.org.uk/> to develop a process to ensure that relevant assays have appropriate validation and QA during protocol development (for both academic and industry trials)
- **Communications:**
 - assist the ECMC Secretariat in developing materials and tools to help identify and communicate relevant capabilities across the ECMC Network (joint objective)
 - advise on how best to keep this information up to date
- **Placements** – feed in to the existing ECMC cross-centre placements and skills sharing scheme. For example looking at publishing who has been on a placement and ensuring that the learning is brought back to the Network. Investigate bursaries for training courses and opening up outside of the ECMC Network. (also TS group)

Translational Science Subgroup

Chair: Karen Swales, ICR

Co-Chair: Fiona Thomson, Glasgow

Remit

- Conducting translational science to the appropriate quality standards
- Sponsoring training courses in relevant 'hot topics' based on assessment of members' needs
- Embracing new developments in translational science by conducting workshops on cutting-edge technologies
- Setting performance standards for biomarker assays
- Identification of promising new techniques and technology
- Rapid adoption and development of new technologies

Objectives

- **New Technologies:**
 - Develop and own process to identify promising new techniques and technologies
 - Advise the ECMC Secretariat on process to assist on early adoption
 - Advise ECMCs on technology adoption
- **Produce a guidance document on assay validation** – possibly with two parts to it – looking at the steps in a validation plan and technical guidance. This work could lead to a publication
- **Communications:**
 - assist the ECMC Secretariat in developing materials and tools to help identify and communicate relevant capabilities across the ECMC Network (joint objective)
 - Advise on how best to keep this information up to date
- **Provide advice on the future direction of the ECMC Network**