QATS 25th February 2015 Meeting Summary

21 May 2015

The Experimental Cancer Medicine Centre Initiative is jointly funded by Cancer Research UK, the National Institute for Health Research in England and the Health Departments for Scotland, Wales and Northern Ireland

QATS Review Meeting – February 2015

- Representatives from ECMC, CRUK, Belfast, Cambridge, Edinburgh, Glasgow, ICR, KCL, Liverpool, Manchester, Newcastle, Southampton

Aims:

- Review whether the QATS network group has a role within the ECMC
- Review the remit of the QATS Network group to identify core activies to continue or develop in future
- Update the mission statement, remit and objectives
- Identify new chair for the QATS steering committee

Mission Statement & Remit

The QATS Network Group supports and enables ECMCs to conduct translational research to the highest achievable levels of quality and regulatory compliance.

Remit

The QATS group pursues a multi-layered approach to achieving its dual goal of maintaining regulatory compliance whilst conducting translational science to the highest achievable quality standards. Our core activities are:

- **Mentoring centres/members in quality assurance processes. This is achieved through networking, sharing expertise and resources**
- **Sponsoring training courses in relevant 'hot topics' based on assessment of member needs**
- **Keeping abreast of new developments in the regulatory domain, by adopting an outward stance and actively engaging key stakeholders in the field, including the MHRA, the EMA and BARQA in joint meetings**
- **Embracing new developments in translational science by conducting workshops on cutting-edge technologies**

The group plans to implement, within the Network, a programme of quality assurance and quality control assessments, coupled with setting performance standards for biomarker assays.

This is in order to provide centres with increased collaborative guidance towards compliance, with the ultimate goal of developing an internal ECMC accreditation scheme for all sites.

Keep

- **Mentoring centres/members in quality assurance processes.**
  - Could perform cross centre audits on request from centres to share best practice
  - Enhance networking between centres
- **Keeping abreast of new developments in the regulatory domain**
- **Sponsoring training courses in relevant “hot topics”**
  - Could we use the Cross-centre placement scheme to subsidise attendance to external courses or learn techniques outside the ECMC
- **Workshops on cutting-edge technologies**
  - Start introductory training in new technologies that is not too technical for QA managers

Keep

- **Setting performance standards for biomarker assays**
  - **Writing guidance documents / publications on assay validation**
  - **Introduce cross-centre QA on commonly performed procedures/ technologies**

- **Development of ECMC quality accreditation scheme**
  - **Benefits:**
    - Externally increase stakeholder confidence in laboratories
    - Internally raise the importance of quality and timeframe for assay validation
  - **Long term goal**
  - **Short term: Investigate building criteria into the ECMC protocol development guidelines – evidence of assay validation or validation plan prior to trial start.**

Create

- **Improved communication of translational research capabilities across the network**
  - What is our existing expertise?
  - Advise on techniques and validation
  - Collaboration / out-source

- **Early warning system for new technologies**
  - Share best practice / standardise early
  - Avoid duplication of effort

- **QA and TS sub-groups**

ECMC QATS Network Group

Mission Statement:
Supporting and enabling ECMCs to conduct translational research to the appropriate levels of quality and regulatory compliance, utilising validated, cutting-edge technologies

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 levels of 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

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
- Identification of promising new technologies and techniques
- Rapid adoption and development of new technologies

Mission Statement:

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