10th Anniversary Symposium of the ECMC Quality Assurance and Translational Science (QATS) Network Group

ECMC Annual Network Meeting: 14 May 2014

**REFLECTIONS** on the ECMC QATS Network Group

Jeff Cummings

“A Success Story and Blueprint for the Future”
(ECMC Network Meeting: 2006)

Quality Assurance has become Emblematic of the (ECMC) Network
(ECMC Impact Report 2007-2011)
The Beginning: 2003
European Clinical Trials Directive 2001/20/EC

No Guidance For Laboratories Involved in PK/PD

The Lancet: May, 2003, Volume 361, Page 1568
The Death of Academic Clinical Trials

Panic Stations – What Do we Do?


The Clinical Trials Directive is arguably the most heavily criticised piece of EU-legislation in the area of pharmaceuticals. This criticism is voiced by all stakeholders - patients, industry, and academic research - Circa 2012.
Pulling together on Quality Assurance (QA) in the Laboratory

A discussion workshop to focus on good clinical and laboratory practice (GCP and GLP) for early phase academic trials in the UK

Wednesday 8 October 2003; Venue: Manchester

Chair: Dr Sally Burtles, Drug Development Office (DDO), Cancer Research UK

09:45 - 10:00  Refreshments and Registration

- The European Union (EU) Directive on Good Clinical Practice (GCP) in the conduct of clinical trials: UK legislation and its impact on academic clinical research  Dr Brian Davies, Medicines and Healthcare Products Regulatory Authority (MHRA)
- Industry's perspective of working with academic laboratories in their clinical trials  Astra Zeneca representative (Andrew Hughes)
- EU Directive – implications for QA in academic trials  Dr Malcolm Ranson, Christie Hospital NHS
- Good Laboratory Practice (GLP) in the academic laboratory  Mr Richard Sugar, Cancer Research UK
- Method validation  Dr Jeff Cummings, PICR

13:00 – 14:00  Lunch

Break into two groups for discussion about validation of assays with particular focus on reporting, specificity, reproducibility and the use of controls for:
Pulling together on Quality Assurance (QA) in the Laboratory

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- Industry's perspective of working with academic laboratories: Astra Zeneca representative (Andrew Hughes)

- EU Directive – implications for QA in academic trials: Dr Malcolm Ranson, Christie Hospital NHS

11:30 – 12:00 Refreshments

- Good Laboratory Practice (GLP) in the academic laboratory: Mr Richard Sugar, Cancer Research UK

- Method validation: Dr Jeff Cummings, PICR

13:00 – 14:00 Lunch Break into two groups for discussion about validation of assays with particular focus on reporting, specificity, reproducibility and the use of controls.

Facilitated by:

i) Pharmacodynamics: Dr Tim Ward & Dr Jeff Cummings

ii) Pharmacokinetics: Dr Gavin Halbert & Dr Florence Raynaud

15:20 Discussion with NTRAC and Cancer Research UK about ways forward including future events and web resources
The NTRAC ERA: 2003-2006
Starting Small – Thinking Big

Quality Assurance (QA) Group Inaugural Meeting
2 – 4pm, 21 January 2004
The Seminar Room, Department of Oncology, Royal Free Hospital, London
Co-Chairs: Dr Jeff Cummings, Paterson Institute for Cancer Studies (PICR) and Christie NHS Trust and Dr Lisa Smith, University College London

<table>
<thead>
<tr>
<th>Name</th>
<th>Surname</th>
<th>NTRAC Centre/Organisation</th>
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<tbody>
<tr>
<td>Mark</td>
<td>Bellchambers</td>
<td>Marsden</td>
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<tr>
<td>Alan</td>
<td>Boddy</td>
<td>Newcastle</td>
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<tr>
<td>Jeff</td>
<td>Cummings</td>
<td>Manchester</td>
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<tr>
<td>Paul</td>
<td>Loadman</td>
<td>Leeds-Bradford</td>
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<td>Sarah</td>
<td>Moyle</td>
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<td>Anna</td>
<td>Olsen</td>
<td>Oxford</td>
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<td>David</td>
<td>Propper</td>
<td>Cambridge</td>
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<td>Cathy</td>
<td>Ratcliffe</td>
<td>NTRAC</td>
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<td>Florence</td>
<td>Raynaud</td>
<td>Marsden</td>
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<td>Lisa</td>
<td>Smith</td>
<td>UCL</td>
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<td>Jane</td>
<td>Steele</td>
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<td>Richard</td>
<td>Sugar</td>
<td>CRUK</td>
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<td>David</td>
<td>Vigushin</td>
<td>Imperial</td>
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Back to the Future: 2003-2014
You Don’t Stay Ahead by Standing Still

- EU Directive 2001/20/EC
- UK SI1031
- MHRA Guidance Silver Guide
- Revised EU 2012/0192 (COD)
- ntrac
- ECMC
- Quality Assurance (QA)
- Bioanalysis (BAQA)
- Translational Science (QATS)
The QA Group Fully Embraced the NTRAC Ethos

- Providing One Stop Support, Resources and Funding
- Facilitating Networking and the Sharing of Best Practise
- Providing Educational Platforms
- Interacting with the Greater Cancer Research Community
- Raising to new Challenges, Constantly Developing
- Reducing Bureaucracy
Facilitating Networking and the Sharing of Best Practise

ntrac QA Group Meetings

<table>
<thead>
<tr>
<th>Date</th>
<th>Venue</th>
<th>Topic</th>
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<tr>
<td>Jan 04</td>
<td>UCL</td>
<td>Preparing for MHRA GMP Inspection</td>
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<td>May 04</td>
<td>Newcastle</td>
<td>Ensuring Quality of Clinical Samples</td>
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<td>Oct 04</td>
<td>Southampton</td>
<td>Document Control/Elispot Validation</td>
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<td>Feb 05</td>
<td>Birmingham</td>
<td>The Birmingham MHRA Inspection</td>
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<td>Jun 05</td>
<td>Leeds-Bradford</td>
<td>Clinical Trials and Tribulations</td>
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<td>Nov 05</td>
<td>Cardiff-Swansea</td>
<td>Manufacturing Exosomes for Trials</td>
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<tr>
<td>Mar 06</td>
<td>ICR</td>
<td>CR UK Audit: Sharing the Experience</td>
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## Providing Educational Platforms; Interacting with the Greater Cancer Research Community; Providing Funding

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>TRAINING</strong></td>
<td>NTRAC/CR-UK/BARQA Training Course on Implementing Good Clinical Laboratory Practice, 7-8&lt;sup&gt;th&lt;/sup&gt; September, 2004, Birmingham, 37 Attendees, Fully subscribed</td>
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<tr>
<td><strong>TRAINING</strong></td>
<td>BARQA Training Course on Introduction to GCLP, 3&lt;sup&gt;rd&lt;/sup&gt; March, 2005, London, 42 Attendees, Fully subscribed</td>
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<tr>
<td><strong>NETWORKING</strong></td>
<td>NTRAC/CR-UK Workshop (with Nurses Group), Manchester, 12th January 06 on “Sample Management in Early Phase Clinical Trials: closing the gap between the clinic and the laboratory”. 90 Participants</td>
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<tr>
<td><strong>ENGAGING</strong></td>
<td>CR-UK, MHRA, BARQA, HTA, Nurses Group, IT Group</td>
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<tr>
<td><strong>FUNDING</strong></td>
<td>Educational Grants to QA group Members to Attend Specialist Training</td>
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One Stop Support - Resources

- QA Web Pages: contained most scientific presentations and experience of MHRA inspections posted on the web
- Mail-talk Web Forum
- SOP Register: Titles of 207 SOPS submitted by 6 different centres posted online. Full copies made available to group members upon request
- Standards: Assay technology; method validation
“Dear Jeff. We look forward very much to working with you and to taking forward the excellent initiatives instigated by your group”.

Director of Translational Research, Cancer Research UK
The BAQA Group: 2007 - 2012

The Bioanalysis and QA (BAQA) Group

A Bolder Vision, A Broader Remit

Comply
QA Mentoring

Validate
Hot Topics In Bioanalysis

Assess
External Audit Programme

Control
Assay Standards Quality Control

Qualify
ECMC Accreditation
BAQA Continuing a Winning Formula

Training Courses
- GCLP - Dec 07
- GCLP - Sep 10
- CSV - Jun 08

Group Meetings
- London - 07
- Liverpool - 07
- Southampton - 08
- Newcastle - 09
- Leicester - 09
- Edinburgh – 09
- London - 11

Workshops
- Method Validation - Mar 09
- Sample Handling - May 10
- Regulatory Issues - Oct 10
- Quality Assurance - May 12

Networking
- BARQA
- CR_UK

Infra Structure Support
- ECMC Website - 08
- BAQA Group Mailtalk - 09
- SOP Register - 11

Networks
- Networking
- MHRA
- Nurses & Ops Groups
- EMA

BAQA Group Publication

BCJ - British Journal of Cancer
The QATS Group: 2012 -2014

Building on the Ambition of the BAQA Group: When Less is More?


2. Group meeting showcasing centre expertise: Biomarkers Fit for Purpose: Belfast, October, 2012

3. ANM Translational Analysis from Consent to Publication: London, May, 2013


5. GCP Training Day: London, Nov, 13

6. QA Managers Meeting, London, March, 14
However, We Have Plan !!!!!

**Medium-term (2014 – 2016)**

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<th>Category</th>
<th>Aim</th>
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<tr>
<td><strong>Mentoring</strong></td>
<td>Continued development of pilot schemes (placements and buddying system)</td>
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<tr>
<td><strong>Cutting-edge Technologies</strong></td>
<td>Continued development of communication about available expertise/validated assays</td>
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<tr>
<td><strong>Training</strong></td>
<td>Two workshops per year – centre based expertise</td>
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<tr>
<td><strong>Training</strong></td>
<td>One workshop per year – recurring themes e.g. compliance issues, biomarker validation, CSV</td>
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<tr>
<td><strong>Best Practice</strong></td>
<td>Harmonisation of biomarker validation policy across ECMC Network</td>
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<td><strong>Best Practice</strong></td>
<td>ECMC approved quality standard – badge of quality of all ECMC labs that meet the requirements</td>
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<tr>
<td><strong>Mentoring</strong></td>
<td>Sharing appropriately trained staff when in need of additional staff (locum or to gain experience)</td>
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Summary

- Many Individuals have worked hard over the last 10 years to sustain the QA group, and as the Present Chair, I would like to extend my whole hearted gratitude to everyone.

- However, it is the future challenges that are important: sustaining funding, maintaining the prestige of QA, keeping the group active and the membership engaged, and continuing to underpin the increasingly complex demands of translational science.

- We have the new EU Clinical Trials Directive to cope with – Paul Stewart.

- Is the future Biomarkers – I am not sure everyone is convinced – Andrew Hughes.

- Will we be measuring companion diagnostics in Academia or will it remain the remit of (contract) Diagnostic Labs - Stuart McWilliams.

- Perhaps the strongest contender will be personalised medicine - David Chang.

- We urgently need new anticancer drugs, so what are the advantages of the pharmacological audit trail - Johan De Bono.