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)

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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

The Academy of Medical Sciences

Panic Stations – What Do we Do?

FORUM : European Clinical Trials Directive; 3 June 2003, London

EUROPEAN COMMISSION

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.

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Stage 1: JC Approaches the Head of NTRAC with the Proposal of Devoting a Scientific Workshop to Quality Assurance (QA)

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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:

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Stage 2: JC Proposes the Concept of the First Network Group that Meets of a Regular Basis

Typical NTRAC Workshop 30-40 Delegates, the QA Workshop 95 Delegates

Pulling together on Quality Assurance (QA) in the Laboratory

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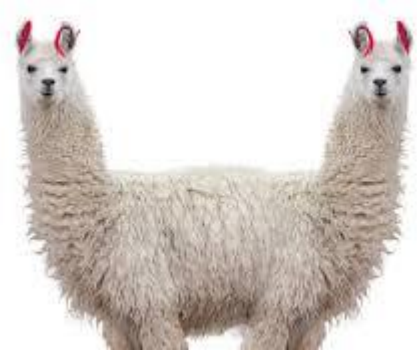

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Cathy Radcliffe

Jeff Cummings

Richard Sugar

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

Name	Surname	NTRAC Centre/Organisation
Mark	Bellchambers	Marsden
Alan	Boddy	Newcastle
Jeff	Cummings	Manchester
Paul	Loadman	Leeds-Bradford
Sarah	Moyle	Southampton
Anna	Olsen	Oxford
David	Propper	Cambridge
Cathy	Ratcliffe	NTRAC
Florence	Raynaud	Marsden
Lisa	Smith	UCL
Jane	Steele	Birmingham
Richard	Sugar	CRUK
David	Vigushin	Imperial

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)**

2001 | 2003 | 2004 | 2007 | 2009 | 2012 | 2016

ntrac NATIONAL TRANSLATIONAL CANCER RESEARCH NETWORK | ECMC | ECMC | ?

Quality Assurance (QA) | Bioanalysis (BAQA) | Translational Science (QATS)

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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

Date	Venue	Topic
Jan 04	UCL	Preparing for MHRA GMP Inspection
May 04	Newcastle	Ensuring Quality of Clinical Samples
Oct 04	Southampton	Document Control/Elispot Validation
Feb 05	Birmingham	The Birmingham MHRA Inspection
Jun 05	Leeds-Bradford	Clinical Trials and Tribulations
Nov 05	Cardiff-Swansea	Manufacturing Exosomes for Trials
Mar 06	ICR	CR UK Audit: Sharing the Experience

Providing Educational Platforms; Interacting with the Greater Cancer Research Community; Providing Funding

TRAINING	NTRAC/CR-UK/BARQA Training Course on Implementing Good Clinical Laboratory Practice, 7-8th September, 2004, Birmingham, 37 Attendees, Fully subscribed
TRAINING	BARQA Training Course on Introduction to GCLP, 3rd March, 2005, London, 42 Attendees, Fully subscribed
NETWORKING	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
ENGAGING	CR-UK, MHRA, BARQA, HTA, Nurses Group, IT Group
FUNDING	Educational Grants to QA group Members to Attend Specialist Training

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

Passing the Baton: The ECMC ERA, 2007 - 2014

03 August 2006

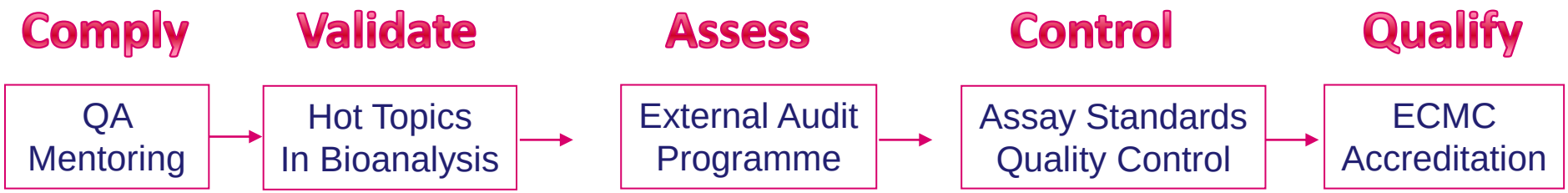
"Dear Jeff. We look forward very much to working with you and to taking forward the excellent initiatives instigated by your group".

Director of Translational Research, Cancer Research UK

The BAQA Group: 2007 - 2012

The Bioanalysis and QA (BAQA) Group

A Bolder Vision, A Broader Remit



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

Networking

MHRA

Nurses & Ops Groups

EMA

BJC British Journal of Cancer

BAQA Group Publication

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The QATS Group: 2012 -2014

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

1. ANM Workshop: Controlling Quality in Biomarker Analysis from Sample Collection and Analysis to the Release of Data: London, May, 2012

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

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

4. ECMC QA Accreditation Discussion: London, Feb, 2013

5. GCP Training Day: London, Nov, 13

6. QA Managers Meeting, London, March, 14

KEEP CALM BECAUSE WE HAVE A PLAN

However, We Have Plan !!!!!

Medium-term (2014 – 2016)

Category	Aim
Mentoring	Continued development of pilot schemes (placements and buddying system)
Cutting-edge Technologies	Continued development of communication about available expertise/validated assays
Training	Two workshops per year – centre based expertise
Training	One workshop per year – recurring themes e.g. compliance issues, biomarker validation, CSV

Long-term (2016 – 2017)

Category	Aim
Best Practice	Harmonisation of biomarker validation policy across ECMC Network
Best Practice	ECMC approved quality standard – badge of quality of all ECMC labs that meet the requirements
Mentoring	Sharing appropriately trained staff when in need of additional staff (locum or to gain experience)

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