



cCOG Team Charter

Team Purpose

This team was formed: To represent commercial sponsors and industry partners of clinical trials and ensure the UK remains competitive and a key player in the global clinical trials environment.

We exist to: Develop common understanding and support for streamlining clinical trial conduct in UK, promote knowledge sharing and identify best practices.

We work to: Support UK initiatives through delivering on our cCOG objectives.

In a way that: Promotes active patient and investigator participation in delivering quality research in the UK.

Vision

To **promote and facilitate** commercial clinical research in the UK in **partnership with NHS organisations** to ensure **highly competitive performance** within the global arena by delivering to **time and quality**.

Operating Guidelines

How we interact/communicate:

cCOG holds quarterly face to face meetings at the ABPI Offices, London. These may be supplemented by ad hoc team/sub-team teleconferences should the need arise.

Members are required to attend a minimum of 3 meetings annually in order to retain membership and absences should be covered by an appropriate delegate from their organisation.

Meeting minutes, including presentations from guest speakers (with their permission), will be distributed to all Member Companies.

cCOG will make available the cCOG Charter, list of Member Companies, a summary of the current year's Objectives, listing of future Meeting Dates and details of meeting topics and presenter (by permission) after each meeting through postings on the cCOG area of the NHS Research Scotland (NRS) and Health and Care Research Wales website(s).

cCOG information and updates can be found at the following links

[NHS Research Scotland/Industry](#)

[Health and Care Research Wales/Industry](#)

Members are encouraged to use the cCOG meeting minutes to provide cCOG updates with colleagues and when representing cCOG at other forums/meetings (see below).

	<p>Members represent cCOG through attendance at; R&D Forum, CREN, Road Map Group and Costing Group meetings.</p> <p>It is noted that cCOG abide by UK Competition Laws.</p>
<p>2017 Meeting Dates</p>	<p>Meeting dates for 2017 have been confirmed as Thursday 2nd February, Friday 23rd June, Friday 15th September and Thursday 9th November.</p> <p>Topics covered will be posted within 1 week following each meeting.</p>
<p>Member Companies</p>	<p> Member Companies_Non-Indu</p>
<p>Roles and Responsibilities</p>	<p>Rotating Chair Will be assigned at each meeting to host the following meeting, in liaison with our ABPI host.</p> <p>The Chair is responsible for formulating the agenda, liaising with members to present news and updates and/or guest speakers covering topics identified by the members.</p> <p>The Chair will distribute the agenda a minimum of 1 week in advance of the meeting and support the logistics with our ABPI host.</p> <p>The Chair will collate speakers' presentations in advance and host the meeting.</p> <p>Rotating Minute Taker Assigned at each meeting to prepare for and take minutes during the meeting, using the cCOG meeting Minutes powerpoint template, which will be distributed to members within 15 working days of the meeting.</p> <p>Members If unavailable to attend in person, members will ensure the ABPI host/rotating Chair are informed in advance, providing details of their delegate.</p> <p>Members unable to attend at least 3 annual meetings should identify a replacement from their Company or their Company will be withdrawn from membership of cCOG.</p> <p>All members are required to actively support the cCOG meeting and objectives.</p> <p>Non-sponsor members Include representatives from ABPI, NIHR, NRS, Health and Care Research Wales and HRA representatives, who provide news and updates relevant to their organisation.</p>

<p>cCOG Objectives</p>	<p>Objectives: cCOG members will agree annual objectives that will be supported each year by a sub-team of members.</p> <p>Members will take steps to deliver on the objectives and report back to members during cCOG Meetings. At the last meeting of the year a final review/close out of the objectives will be conducted.</p> <p>New objectives, which may include those extended from the previous year, will be agreed at the first annual meeting.</p> <p>The 2017 objectives are detailed below (meeting overview).</p>
<p>Key Stakeholders</p>	<ul style="list-style-type: none"> • ABPI • CREN • RMG • R&D Forum • HRA • NIHR • NRS • NICRN • Health and Care Research Wales
<p>2017 Meeting Overview</p>	<p>2017 Meeting Summary - Friday 23rd June, presenters detailed below have given consent to be contacted for more information in relation to topics -</p> <ul style="list-style-type: none"> • Alastair Nicholson and Janet Messer, HRA, provided updates on the revisions to HRA website (due end July), single mCTA accepted by all devolved nations development, combined IRAS form, replacing the separate REC and R&D forms across the UK, will launch 28th June and the latest on the Master Indemnity Agreement as it pertains to clinical research in England. • Lydia Vitolo, Senior Industry Manager for Health and Care Research Wales, confirmed the centralisation of contracting and costings across Welsh sites was ongoing including defining the format of ‘capacity and capability’ statements, which will be in place from September 2017. With respect to consolidation of feasibility services across UK, for the time being companies are advised to submit to Wales & Scotland directly. • Updates for NRS on behalf of Steven Burke included NRS website updates, NRS commitment to single mCTA development and collaboration with cCOG looking at feasibility in Scotland. • Lorraine Fincham, Commercial Research Initiative Manager, shared updates from NIHR including details of the single feasibility service that will be offered across the devolved administrations through a single submission and revisions to the early feasibility and site intelligence services, which will be piloted with a selection of Pharma and CRO companies. • cCOG members confirmed 2017 objectives: <ul style="list-style-type: none"> ○ Site Readiness and Activation (NEW) – a ‘SIV survey’ has been distributed to member companies’ CRAs ○ Raising Patient and Public Awareness of Clinical Trials (ongoing) – patient ambassadors will be attending the September meeting to present on their role within clinical research. ○ Data Quality in Clinical Trials (ongoing) – pilot survey returned from sites, team to analyse and present back in September. Plan to engage with NIHR to focus on and improve UK metrics. ○ Support optimal Clinical Trial Conduct in the UK through a rapid, smooth and clear HRA approval process both at study set up and amendments approvals (expanded from 2016) – guidance in the form

of a flowchart outlining how amendments should be managed across devolved nations is in development.

- cCOG will enquire about posting information on the NICRN Industry website.
- Hot topics –
 - Members were made aware of the planned introduction of expanding ‘credentialing’ register to research, whereby clinical trial staff attending NHS sites will need to be registered before being allowed on site to monitor – Janet Messer is collecting feedback from cCOG members for a meeting with NHS England early July.
 - The General Data Privacy Regulation (GDPR) will be in force from May 2018, all companies will need to be ready to meet the new requirements -See www.eugdpr.org for more information on GDPR.

Next meeting 15th September 2017.

If you would like to find out more about cCOG or wish to enquire about membership - please feel free to contact us at CommercialCOG@outlook.com