



## 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 engaging with key players in the UK clinical research environment.

**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 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, listing of future Meeting Dates and details of meeting topics and presenter (by permission) after each meeting through postings on the **Industry pages of NHS Research Scotland (NRS) and Health and Care Research Wales websites**.

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&amp;D Forum, CREN, Road Map Group and Costing Group meetings.</p> <p>It is noted that cCOG abide by <b>UK Competition Laws</b>.</p>
<p>2018 Meeting Dates</p>	<p>Meeting dates for 2018 have been confirmed as Monday 5<sup>th</sup> February, Tuesday 12<sup>th</sup> June, Wednesday 26<sup>th</sup> September and Tuesday 12<sup>th</sup> December.</p> <p>Topics covered will be posted within 1 month of the meeting.</p>
<p>Member Companies</p>	<p style="text-align: center;">   Member  Companies_Non-Indu </p>
<p>Roles and Responsibilities</p>	<p><b>Rotating Chair</b>  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><b>Rotating Minute Taker</b>  Assigned at each meeting to prepare for and take minutes during the meeting, using the cCOG meeting Minutes power point template, which will be distributed to members within 15 working days of the meeting.</p> <p><b>Members</b>  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 call for feedback/engagement in initiatives and working groups associated with the UK clinical trial environment.</p> <p><b>Non-sponsor members</b>  Include representatives from ABPI, NIHR, NRS, Health and Care Research Wales and HRA, who provide news and updates relevant to their organisation.</p>
<p>cCOG Objectives</p>	<p><b>Objectives:</b> When deemed relevant, cCOG members will develop and contribute to objectives that are aimed at delivering improvements within UK clinical trials.</p>

	<p>cCOG members have agreed that for 2018, objectives will not be set – instead meetings will become more interactive and focus on opportunities to discuss hot topics, shared experiences and best practices.</p>
<p>Key Stakeholders</p>	<ul style="list-style-type: none"> <li>• ABPI</li> <li>• CREN</li> <li>• RMG</li> <li>• R&amp;D Forum</li> <li>• HRA</li> <li>• NIHR</li> <li>• NRS</li> <li>• NICRN</li> <li>• Health and Care Research Wales</li> </ul>
<p>2018 Meeting Overview</p>	<p>2018 Meeting Summary – Tuesday 12<sup>th</sup> June, presenters detailed below have given consent to be contacted for more information in relation to topics -</p> <ul style="list-style-type: none"> <li>• <a href="#">Alastair Nicholson</a>, Senior Development Manager for HRA, provided details on; the <b>Service Improvement Programme</b> (SIP) looking at integration of REC and HRA assessment as a single service, preparing for the impact of EU CTR/BREXIT, the ‘new IRAS’ system anticipated 1<sup>st</sup> April ‘19, plans to implement the ‘single cost/contract’ following the NHS England consultation, the future focus on the management of amendments working alongside CREN and finally an update on GDPR situation</li> <li>• <a href="#">Lydia Vitolo</a>, Senior Industry Manager and <a href="#">Matthew Harris</a>, Research Engagement Lead, both of Health and Care Research Wales, confirmed that Wales have aligned processes and documentation with England in relation to NHS R&amp;D Approval. From 16<sup>th</sup> April ‘18 HRA/HCRW approval will apply to NHS organisations in England and Wales – with no requirement for separate reviews in either country. NHS permission/SSI submission is no longer required within Wales and Welsh sites will confirm capability and capacity (C&amp;C) by signing of contracts, as for English sites. Sponsors should provide Welsh sites a copy of the local information packs (LIP) to allow C&amp;C to be given. Implementation of the UK LIP has been delayed due to the development of the UK e-submission for study applications, aimed to be implemented end June/early July ‘18. Welsh sites are also aligned on implementation of amendments if no objection raised within 35 days. Wales are continuing work on the single contract, one cost approach as exists in Scotland, delivery of this model planned 1<sup>st</sup> October (in-line with NIHR timelines for implementation of same in England) and fully aligned with the single UK-wide feasibility process.</li> <li>• <a href="#">Steven Burke</a>, Industry Liaison Manager for NRS, confirmed the positive engagement from NRS with the UK alignment on feasibility services offered by the networks and spoke of the plans for a single CDA covering all Scottish Health Boards to allow easier sharing of information.</li> <li>• <a href="#">Divya Chadha Manek</a>, Head of Commercial Business Development for NIHR, provided an update on the <b>National Improvement Plan</b>. Three workstreams – Stakeholder Engagement, Commercial Effective Study Set Up and Performance Monitoring and Target Setting, launched this year in response to feedback from cCOG aimed at improving communication with Industry and clarifying the services offered across the 15 CRNs. Divya also outlined NIHR involvement in delivering on the NHS England consultation with a single contract/cost for</li> </ul>

studies across England by 1<sup>st</sup> October, with launch planned for 10<sup>th</sup> October during the NIHR CRN National Industry Event 2018

- NHS Costing template is being revised and will be available as a fully on-line tool – dates TBC. The 18/19 update to the NHS Costing Template includes a revision to the fees for training, inclusion of apprenticeship levy in salary rates and change to 'admin' staff banding. Further refinement of the template is ongoing through development of a specification for an online version of the NHS Costing template which will also incorporate updates to the investigation price list and a full Pharmacy section which are currently ongoing.
- Hot topics discussed included ARSAC delays in issuing licenses, EU CTR update, Capacity and Capability sign off delays and the single MREC/HRA submission/new IRAS.

Next meeting Wednesday 26<sup>th</sup> September 2018.

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](mailto:CommercialCOG@outlook.com)