



## 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, <b>Wednesday 26<sup>th</sup> September</b> 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 and NHS R&amp;D Forum, 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 – Wednesday 26<sup>th</sup> September, 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; Brexit &amp; plans for CWOW to allow a single submission covering ethics, HRA and MHRA, ARSAC and proposals to resolve delays in issuing Institution licenses, launch plans for the new GDPR compliant mCTA and the status on NHSE consultation.</li> <li>• <a href="#">Lydia Vitolo</a>, Senior Industry Manager, Health and Care Research Wales, provided news on Welsh ongoing plans for alignment with England and requirement to use mCTA template (as for England) and status on the ‘one cost one contract’ approach in Wales.</li> <li>• <a href="#">Steven Burke</a>, Industry Liaison Manager for NRS, updated cCOG on the single CDA for Scotland approach covering all 14 health boards that should be available mid Oct18, which is non-mandatory and the alternative is to establish CDA with each HB. The Scottish generic review group are investigating to ensure alignment with England/Wales. Further Scottish R&amp;D finance departments have escalated the issues they face with invoicing from different sponsors with the intention to engage sponsors and simplify the process.</li> <li>• <a href="#">Lorraine Fincham</a>, Head of Commercial Business Development for NIHR, provided an update on the <b>National Improvement Plan</b> and shared life sciences industry - YouTube webinar promotion :  <a href="https://www.youtube.com/watch?reload=9&amp;v=r1_6ZNKsEwU&amp;feature=youtu.be">https://www.youtube.com/watch?reload=9&amp;v=r1_6ZNKsEwU&amp;feature=youtu.be</a> including a reminder of the NIHR CRN National Industry Event 2018, 10<sup>th</sup> October.</li> <li>• Clinical Trial Specialist Apprenticeship Degree was reviewed – the Trailblazer group was established March 2017 looking to utilise the apprenticeship levy funds that Industry are required to pay, which can be used to fund the £26K five year degree course with institutes of Higher Education (relevant in England only). To date, trailblazer group companies are able to offer ~20 places from Sept '19.</li> <li>• Feedback from members attending key stakeholder groups –</li> <li>• NHS Costing team have been disbanded pending the new on-line costing tool, which will be critical in supporting the new ‘single cost’ model across NHS England. The latest costing template (effective 3<sup>rd</sup> October) has some additional detail – it is recommended to use for all new studies from 1<sup>st</sup> October rather than to switch over for any ongoing negotiations.</li> <li>• RoadMap Group shared revised ‘Site Identification’ form which now covers social care, Primary and Secondary care. ABPI offer ‘Brexit Updates’ monthly</li> </ul>

	<p>calls reviewing impact on Industry and general overview. September meeting was the first RMG meeting where NRS and HCRW attended.</p> <ul style="list-style-type: none"><li>• Summary slides from R&amp;D Forum group were made available to the cCOG members – representatives from R&amp;D Forum will be attending future meetings.</li><li>• Hot topics discussed included Caldicott reviews being performed at some Trusts, acceptance of e-signatures on study contracts, equipment indemnity issues, industry BREXIT preparation activities, sites' acceptance of risk-based monitoring and format for site file document archiving as CDs are no longer valid amongst other topics</li></ul>
	Next meeting Wednesday 12 <sup>th</sup> December 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)