| | |
|---|---|
| | **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.<br><br>**We exist to**: Develop common understanding and support for streamlining clinical trial conduct in UK, promote knowledge sharing and identify best practices.<br><br>**We work to**: Support UK initiatives through engaging with key players in the UK clinical research environment.<br><br>**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:**<br>cCOG holds quarterly face to face meetings. These may be supplemented by ad hoc team/sub-team teleconferences should the need arise.<br><br>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.<br><br>Meeting minutes, including presentations from guest speakers (with their permission), will be distributed to all Member Companies.<br>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 & Care Research Wales websites.**<br><br>cCOG information and updates can be found at the following links<br>NHS Research Scotland/Industry<br>Health and Care Research Wales/Industry<br><br>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). |

| | |
|---|---|
| | Members represent cCOG through attendance at; R&D Forum, CREN, Road Map Group and Costing Group meetings.<br><br>It is noted that cCOG abide by **UK Competition Laws.** |
| 2019 Meeting Dates | Meeting dates for 2019: 6th March and 5th June – Q3/4 TBC<br><br>Topics covered will be posted within 1 month of the meeting. |
| Member Companies | Member Companies_Non-Indu |
| Roles and Responsibilities | **Rotating Chair**<br>Will be assigned at each meeting to host the following meeting, in liaison with our ABPI host. From 2019 ABPI will no longer host cCOG meetings, which will be held at Industry members' offices.<br><br>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.<br>The Chair will distribute the agenda a minimum of 1 week in advance of the meeting and support the logistics with our ABPI host.<br>The Chair will collate speakers' presentations in advance and host the meeting.<br><br>**Rotating Minute Taker**<br>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.<br><br>**Members**<br>If unavailable to attend in person, members will ensure the ABPI host/rotating Chair are informed in advance, providing details of their delegate.<br><br>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.<br><br>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.<br><br>**Non-sponsor members**<br>Include representatives from ABPI, NIHR, NRS, Health & Care Research Wales and HRA and NHS R&D Forum, who provide news and updates relevant to their organisation. |

| | |
|---|---|
| cCOG Objectives | **Objectives:** When deemed relevant, cCOG members will develop and contribute to objectives that are aimed at delivering improvements within UK clinical trials. |
| Key Stakeholders | • ABPI<br>• CREN<br>• RMG<br>• R&D Forum<br>• HRA<br>• NIHR<br>• NRS<br>• Health and Care Research Wales |
| 2018 Meeting Overview | 2018 Meeting Summary – Wednesday 12th December, presenters detailed below have given consent to be contacted for more information in relation to topics -<br><br>• Lydia Vitolo, 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. Lydia confirmed Welsh sites had contributed 80 EoI through combined site ID process with 10 sites awarded studies as a result – Wales are looking to increase this and are keen to engage with sponsors and encourage greater interaction.<br>• Alastair Nicholson, Senior Development Manager for HRA, provided details on; IRAS updates and plans to decouple the new Local Information Pack (LIP) process, which will be introduced in paper format initially and will replace the SSI process currently in use in Scotland and NI by mid-2019, so all UK sites will provide 'Capability and Capacity' confirmation, ongoing plans to implement the single costing model across England with the on-line costing template from April 2019, plans for GDPR compliant mCTA release early 2019, planned meeting with ARSAC to look at ways to streamline this process and a review of CWOW (single submission & approval pilot) progress, which will continue 'by invitation' until planned launch later in 2019.<br>• Charles Weller, General Manager and a.i. Industry Liaison Manager for NRS, shared timelines for implementing the single CDA for Scottish sites (late Spring 2019) and outlined 2019 strategy for continuing alignment with UK, increasing engagement with Industry, consolidating single cost/contract work, encouraging more investigator sponsored studies, focus on start-up times and simplification of invoicing/payment for CTs.<br>• Lorraine Fincham, Head of Commercial Business Development for NIHR, provided an update on the National Improvement Plan with the integration of local and central CPMs systems resulting in sponsor validation of recruitment data from Q2 2019 (as opposed to providing the recruitment data). Need for sponsor to maintain study contact details and be responsive to ensuring CRN hold accurate study performance data to support ongoing performance monitoring and stakeholder engagement. The NIHR Champion Network will be re-introduced 2019 to engage Industry and promote sharing of knowledge and better ways of working. Lorraine's work in biosimilars has indicated a high level of interest across NHS England wishing to be involved.<br>• Feedback from members attending key stakeholder groups - Maria Palmer representing R&D Forum group, shared training opportunities for industry and NHS staff planned for 2019 and a commitment for R&D Forum as member of NIHR/industry stakeholder forum on making UK the best place for clinical trials after Brexit, support of the single cost/contract initiative and the quality of |

| | |
|---|---|
| | amendments/local information packs work with HRA and support streamlined set-up through simplification of CDA requirements.<br><br>• Hot topics included CRA access to electronic medical records for monitoring purposes, ABPI guidance on patient recruitment campaigns and conflict with the code including use of social media for patient recruitment. |
| | Next meeting 6th March 2019 – location Covance, Maidenhead |