UKCRC Registered CTU Network
Core Activities Survey 2015

Core Activities Survey – Executive Summary

This survey addressed the first remit of the core infrastructure working group, namely "to establish consensus across registered CTUs as to what elements of their work comprise 'core' activities".

Core activity was conceptualised and defined as *"essential activity which is not funded through project grant funding but which is vital to the development and support of a portfolio of studies for a registered CTU"*.

The activities presented in this survey were grouped into nine broad categories:-

1. Activities related to study development and grant submission, prior to a trial/study commencing *(19 activities)*
2. Activities post funding decision but before the study starts *(23 activities)*
3. Activities during accrual and active follow-up *(16 activities)*
4. Activities related to data management and analyses *(14 activities)*
5. Activities in preparation for and during study close-down *(11 activities)*
6. Activities related to general management and strategic development of a CTU *(18 activities)*
7. Activities related to training and professional development *(8 activities)*
8. Activities related to methodological development *(4 activities)*
9. Activities comprising 'national/international contribution' *(14 activities)*

For each listed activity, respondents were asked to indicate the strength of their agreement that the activity in question was 'core' on a 5 point scale (strongly disagree – disagree – uncertain – agree – strong agree). The last listed activity in each category was 'other, please specify'. At the end of each section (corresponding to category), respondents had the option to provide free-text comments, elaborating on or explaining their responses.

A web-based survey (SurveyMonkey™) was distributed to the Directors of the UK CRC registered CTUs in April 2014. The survey was closed on 19th May 2014. The

introductory rubric stated: "This survey asks for your views on whether specific activities comprise 'CTU core activity' – i.e. activities which are vital to the development and support of a portfolio of trials and studies, and ensuring that those studies are conducted to the highest quality, and which (in an ideal world) SHOULD NOT be a charge on an individual trial grant from a non-commercial funder."

In analysing responses, consensus that an activity is 'core' was arbitrarily defined as ≥75% 'strongly agree' + 'agree' (a threshold commonly used in other consensus gathering exercises) while consensus that an activity is 'not core' was defined as ≥75% 'strongly disagree' + 'disagree'. Majority views were defined as >50% 'strongly agree' + 'agree' that an activity is 'core' and >50% 'strongly disagree' + 'disagree' that an activity is 'not core'. All other patterns of response were classified as 'equivocal'.

In total, 34 of the 45 registered CTUs responded to the survey, a response rate of 76%. Respondents were of the view that the majority of activities that related to:

- study development and grant submission, prior to a trial/study commencing (category 1)
- general management and strategic development of a CTU (category 6)
- training and professional development (category 7)
- methodological development (category 8)
- 'national/international contribution' (category 9)

were 'core'. By contrast, most activities during accrual and follow-up (category 3), those relating to data management and follow-up (category 4) and (albeit to lesser extent) in preparation for and during study close-down (category 5) were considered to be 'non core'; activities in these categories are typically study-specific and are a legitimate call on individual study grants. There were mixed views over activities that took place post-funding decision but before study start up (category 2), such as applying for ethical and regulatory approvals; comments made in elaboration of scores indicated a considerable amount of effort may be required for these start up activities, but some funders will only release the grant once all permissions are in place.

Core Activities Survey

Methods

This survey addressed the first remit of the core infrastructure working group, namely "to establish consensus across registered CTUs as to what elements of their work comprise 'core' activities". **Core activity** was conceptualised and defined as *"essential activity which is not funded through project grant funding but which is vital to the development and support of a portfolio of studies for a registered CTU".*

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The initial choice of categories and activities therein, and the allocation of activities to categories, was informed by the *Review of current core capacity of UKCRC Registered Clinical Trials Units and future resource requirements for the development and delivery of academic-led, late phase, randomised controlled trials across the UK* conducted in 2008, and refined in discussion between members of the Core Infrastructure Group.

For each listed activity, respondents were asked to indicate the strength of their agreement that the activity in question was 'core' on a 5 point scale (strongly disagree – disagree – uncertain – agree – strong agree). The last listed activity in each category was 'other, please specify'. At the end of each section (corresponding to category), respondents had the option to provide free-text comments, elaborating on or explaining their responses.

The questionnaire was developed for web-based delivery, using the SurveyMonkey™ software; hard copies were available on request, to facilitate review and discussion of items within a CTU, prior to on-line completion. A copy of the questionnaire is included as Appendix A.

A link to the web-based questionnaire was distributed to the Directors of the UK CRC registered CTUs on 10 April 2014 Directors were informed that colleagues could complete the questionnaire on their behalf or contribute to its completion, but that only one response per CTU should be submitted. Following an overview of the survey at the CTU Directors' meeting in May 2014, the deadline for response was extended to 09 May 2014and a reminder email issued
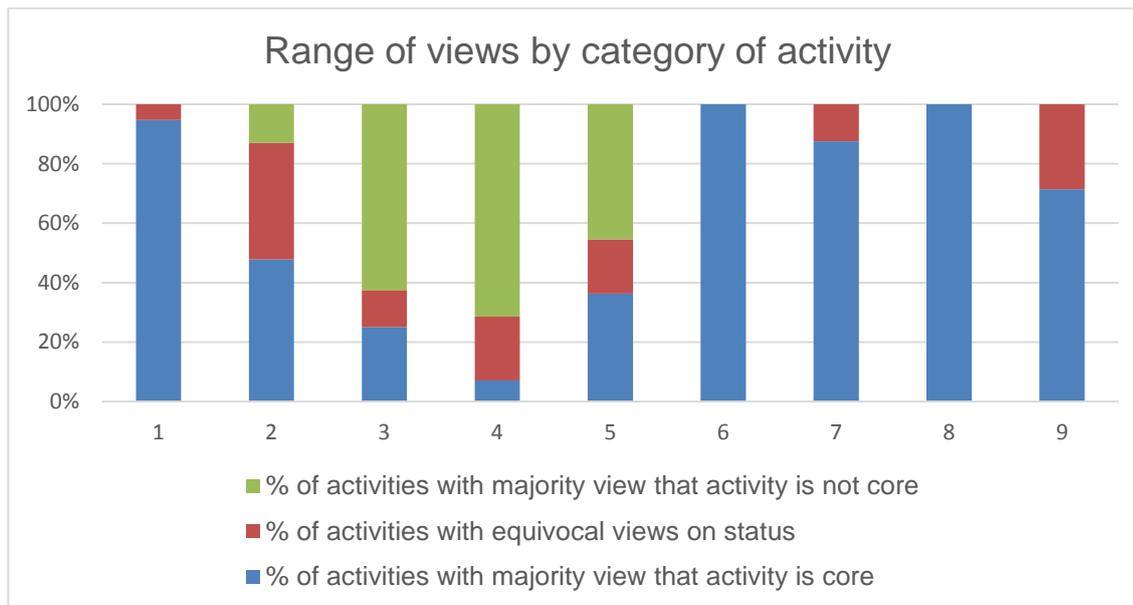
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Findings

In total, 34 of the 45 registered CTUs responded to the survey, a response rate of 76%. Questionnaires were completed between 7th April 2014 and 19th May 2014.

Figure 1 shows the pattern of responses in respect of majority views.

Respondents were of the view that the majority of activities that related to:

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regulatory approvals; a considerable amount of effort may be required for these start up activities, but some funders will only release the grant once all permissions are in place.

Figure 2 shows the pattern of responses in respect of consensus views that activities were core.
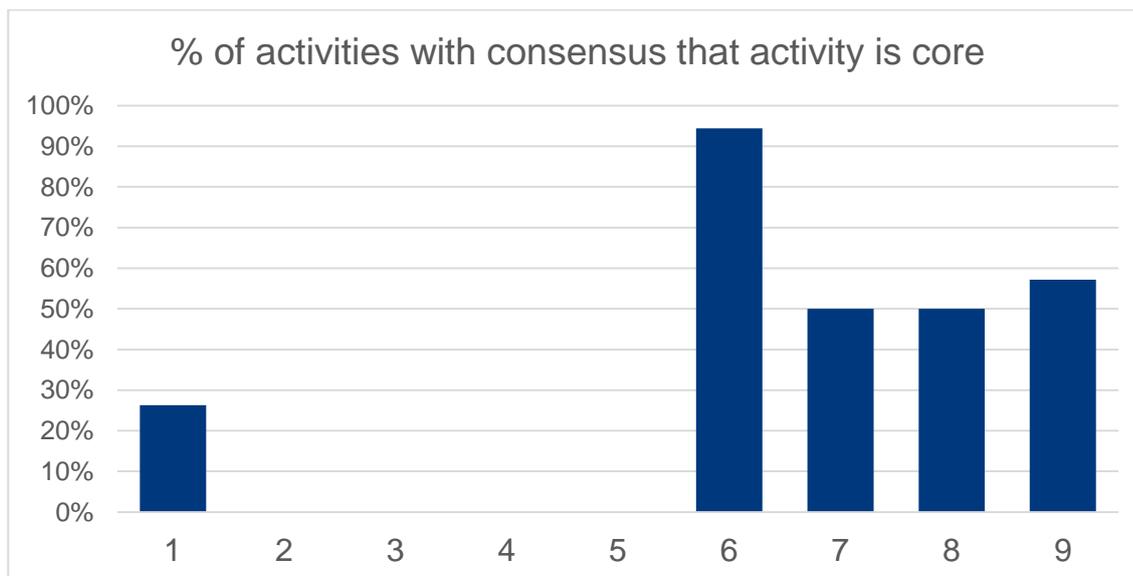
Specific activities considered to be 'core', in order of percentage agreement, with their associated categories and % agreement (i.e. % 'agree' + % 'strongly agree' combined) are as follows:-

Activity	Cat	Agree
Preparation of documentation/reports required for CTU accreditation/ registration	6	100%
Preparation of documentation/reports required for maintenance of CTU external funding sources (e.g. NIHR CTU annual reports)	6	100%
Engagement in CTU management meetings	6	100%
Developing CTU strategy	6	100%
Building, nurturing and maintaining long-term strategic collaborations	6	100%
Development and refinement of trial design & methodology, including definition of endpoints	1	100%
Writing and review of SOPs	6	97%

Central monitoring and management of CTU's portfolio of work	6	97%
Reviewing and responding to general CTU business needs	6	97%
Production and dissemination of CTU brochures/newsletters	6	97%
Other PR activities (networking, conferences etc.)	6	97%
Horizon scanning for new opportunities	6	97%
Identifying CTU staff training needs and oversee training	7	97%
Costing of CTU input for grant submission	1	97%
Review and response to referees' and panel's comments on bids	1	97%
Management of HR functions within CTU	6	94%
Management of CTU finances	6	94%
Development and maintenance of CTU website	6	94%
Delivering training to CTU staff	7	94%
Undertaking own training/development activities	7	94%
Maintaining awareness of trial design developments (through reading, conference attendance etc.)	8	94%
Membership of standing groups or 'task and finish' groups within registered CTUs	9	94%
Membership of TSCs/DMECs for trials outwith own CTU	9	94%
Linking functional and project-specific teams within CTU	6	91%
Trouble-shooting and responding to crises/problems on ad hoc basis	6	91%
Acting as mentor to CTU staff	7	91%
Shaping research agenda via clinical studies groups etc.	9	91%
Preparation of grant proposal	1	91%
Assistance with other (i.e. non-CTU) aspects of costing and budget preparation	1	91%
Peer-reviewing for funding bodies	9	88%
Board/panel membership for funding bodies	9	88%
Management of CTU accommodation/space and other resources	6	85%
Peer-reviewing for journals	9	85%
Promotion of funding opportunities for methodological research	8	82%
Contribution to other advisory and review committees/boards	9	82%
Negotiations with sponsor	1	82%
Providing methodological and other advice to 3rd parties within and outwith host organisation	9	76%

Those with a majority view that the activity is 'core', but not achieving consensus comprise:-

Activity	Cat	Agree
Negotiations and consultations with industry partners	1	74%
Initial work on IMP sourcing	1	74%
Initial work on sourcing of trial devices	1	74%
Conducting research into new/improved approaches to trial design & conduct	8	71%
Conducting research into new/improved approaches to trial analysis	8	71%
Editorial board membership for journals	9	71%
Negotiations and consultations with potential collaborators and sites	1	71%
Study/trial feasibility assessments (including patient pathway)	1	71%
Supervising/supporting studentships/fellows	7	70%
Risk assessment	1	70%
Preparation and support for statutory inspections (e.g. MHRA) and other audits (e.g. R&D)	3	70%
Initial work on other trial intervention development	1	69%
Scoping reviews and systematic reviews to justify trial and support design etc.	1	68%
Negotiations and consultations with research networks	1	68%
PPI work	1	68%
Supervision and senior support of regulatory and ethical applications	2	68%
Delivering CPD courses within own organisation	7	66%
External mentoring/support of other CTUs	9	65%
IP negotiations	1	62%
Supervision and senior support of protocol development and sign-off	2	62%
Supervision and senior support of development of risk assessment and monitoring plan	2	62%
Appointment and training of project staff	2	59%
Contingency support for unexpected circumstances (e.g. staff absences, safety issues etc.)	3	59%
Negotiations and consultations with national and international groups	1	58%
Providing an out-of-hours service (e.g. for SAE reporting, 24 hour randomisation)	6	56%
Budget monitoring	3	56%
Supervision and senior support of preparation of data for data sharing	5	56%

Provision of summary data on request	5	56%
Supervision and senior support of QA activities specific to study	3	55%
Supervision and senior support of IMP sourcing	2	53%
Supervision and senior support of device sourcing	2	53%
Supervision and senior support of development/refinement of other trial intervention	2	53%
Supervision and senior support of CRF development	2	53%
Supervision and senior support of database development & validation	2	53%
Supervision and senior support of sample handling arrangements	2	53%
Supervision and senior support of study recruitment strategy	2	53%
Addressing unforeseen analysis issues	4	53%
Provision of individual (anonymised) patient data on request	5	53%
Supervision and senior support of other dissemination activities	5	53%
Delivering undergraduate courses within own organisation	7	53%

The pattern of responses for all items is shown in Appendix B. Several respondents provided amplifying comments in respect of their responses. Representative free-text comments relating to the categories of activity where the majority view was that they were 'core' are presented below.

Category 1 – Activities related to study development and grant submission, prior to a trial/study commencing

"1. The vast majority of work related to supporting the development and submission of proposals is considered to be core activity and would be supported by senior CTU staff. Some clerical work related to proposal submission is not funded through any other source so would be undertaken by trial funded clerical staff. 2. Support for proposal development including scoping reviews of the literature is core activity but this would not stretch to systematic reviews which require a substantial amount of work. It is difficult to see where this level of work would be funded from. In principle it is core activity but in practice the resources are not sufficient 3. All work related to trial implementation including initial work on documents required for regulatory and ethical approval is funded from trial grants. Some investigators feel that they can do this within their own resources but this often leads to problems down the line and multiple amendments. The trial manager is absolutely required to be involved in this process and this should be funded

from trial grants. It is a serious concern that HTA consider this work can be done prior to release of the trial grant."

"All the work required to develop and submit a high quality grant application are considered core. However initial work up for regulatory and ethics we would hope to recoup from the funder. This is obviously and issue for NIHR funded trials where funding is not released until approvals are in place."

"All aspects of grant preparation, costing, negotiations with collaborators, preparation of protocol, ethics etc. should be led by the CI - always. The CTU should inject specialist expertise into that process, along with other co-applicants. CTU's should not be generic administrators doing the work investigators don't wish to undertake - they should identify staff in their own departments to support the initial admin elements. CTU should attend setup TMG's and advise only, until funding begins."

"It is unlikely that the costs of the grant work-up (particularly for unsuccessful applications) can be clawed back from grant awards. However, these activities are probably a legitimate call on CTU 'pump priming' funding."

Category 6 - Activities related to general management and strategic development of a CTU

"These are all very much to do with running the SME that is a CTU, and therefore are 'core' activities."

"I think these are all clearly 'core' activites and could not reasonably be assigned to any trial funding body."

"Senior CTU staff are funded through core funding and will lead and take responsibility for the majority of these functions. However where duties are preformed by more junior clerical and admin staff and the functions are purely related to running of the CTU and are not related to teaching or academic work these are NOT core functions and would be paid for from trial grants."

Category 7 - Activities related to training and professional development

"The supervision of students/ fellows is an academic activity that is not necessarily a core function of a CTU, but may be a role of its academic staff, and resourced by the host HEI."

"While I believe the above activities are CORE (and vital) they are often neglected as we don't have sufficient resource to get the head room to develop courses or training. We'd love to offer internships but don't have the time to design the package!"

"There is existing provision for statisticians and other academic staff to deliver undergraduate and postgraduate training outside the CTU but non-statistician staff are not on academic contracts and should not be expected to deliver this support as core activity. If teaching is requested, it should be fully funded."

"We would obviously consider training and development of CTU staff as core, but would expect to charge for providing external training."

"Whilst supporting students is part of core activity, there should be comparable funding available to bench fees for laboratory based students."

Category 8 - Activities related to methodological development

"Whilst much of this activity is core, there should be specific funding streams to allow methodological development and to support attendance at conferences."

"We are keen to develop our in house research activity but don't have the head room. If we had a research fellow in house (CORE funded or otherwise) to build on the trial within a trial approach, we'd do a lot more of this and use it to promote best practice within our unit and throughout the network, just not sure if it's core."

"Methodological research should be funded like any other research. Core activity should include taking part in methods projects but leading such projects is not core."

"Although there is agreement to core status for most of the above questions, there are likely to be opportunities to also incorporate project funding as well - - no clear boundaries. and so probably needs to be flexible."

"Ideally, external funding for research into new / improved approaches to trial design, conduct and analysis but if there is an opportunity, on a smaller scale within individual projects, then we are keen to utilise from core funding."

Category 9 - Activities comprising 'national/international contribution'

"Again, peer review etc may be roles a CTU's academic staff may chose to take on but not core CTU activities. Host HEIs would not necessarily support external education activity that is in conflict with own courses."

"Several of the above activities are areas we're keen to be involved in but once again, it comes down to a lack of resource. With limited CORE funding, we're having to use the resource wisely and not spread ourselves too thinly. If we had additional CORE funding, we could broaden our interactions from local groups (fire fighting) to having an increased stake in the wider trial network and actually influence trial management, delivery and budget with the organisations that are calling for the research, letting them know they are getting value for money. Some activities remain trial specific and should be funded. However, use of CORE resource to provide the infrastructure for triallists during the early stages of project development will ensure well thought out, scientifically valid projects, with achievable patient pathways, are presented to funders. These will have a realistic budget that will give sufficient resource so the studies can be delivered on time and to target."

"Although these answers are predominantly core - --in part this is reflective that they should not be project based charges. In all likelihood, there would be other sources of external / institutional funding which would make significant contributions to the support of these activities."

"I agree with all of these because CTU need to be seen as academic related departments and not just a service. We are expected to do all of the above in effect without dedicated time or funding. That isn't going to work, and I do not see e.g. the MRC Methodology Hubs delivering this to the fullest extent."

"We tend to take the view that if the activity has a direct or strong indirect benefit to the CPD or profile of CTU staff or the profile of the CTU itself then it is core. Other activities that utilise the expertise of CTU staff e.g. mentoring, teaching, training etc, we would expect to charge for."

"Activities marked as disagree should be covered by existing HEFCE funded staff outside the CTU or should be appropriately funded. This should not be core CTU activity, funded from NIHR NETSCC or from project grant resource."

General comments

"Particular areas of contention appear to be finance, admin and QA support. These are seen by the host organisations as related to delivery of CTU activity and therefore to be funded from grants. Core funding is provided for senior management, strategic development and proposal development and grant capture."

# Appendix B – Pattern of responses for all questions

- % agreement = % 'agree' + % 'strongly agree'
- % uncertain = % 'unsure"
- % disagreement = % 'disagree' + % 'strongly disagree'
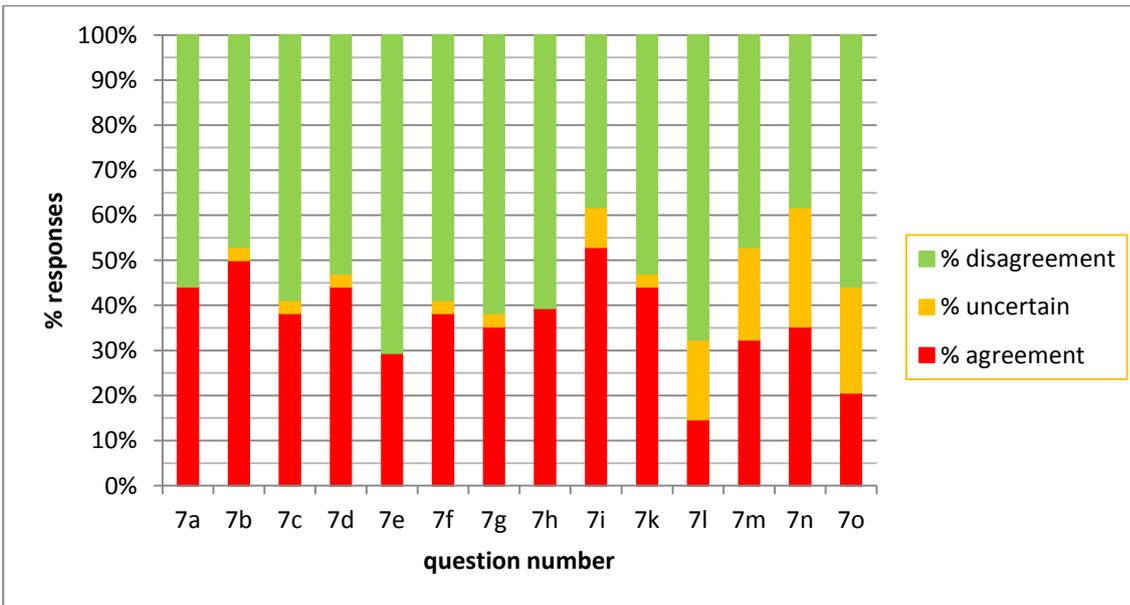- Question numbers refer to the numbering in Appendix A
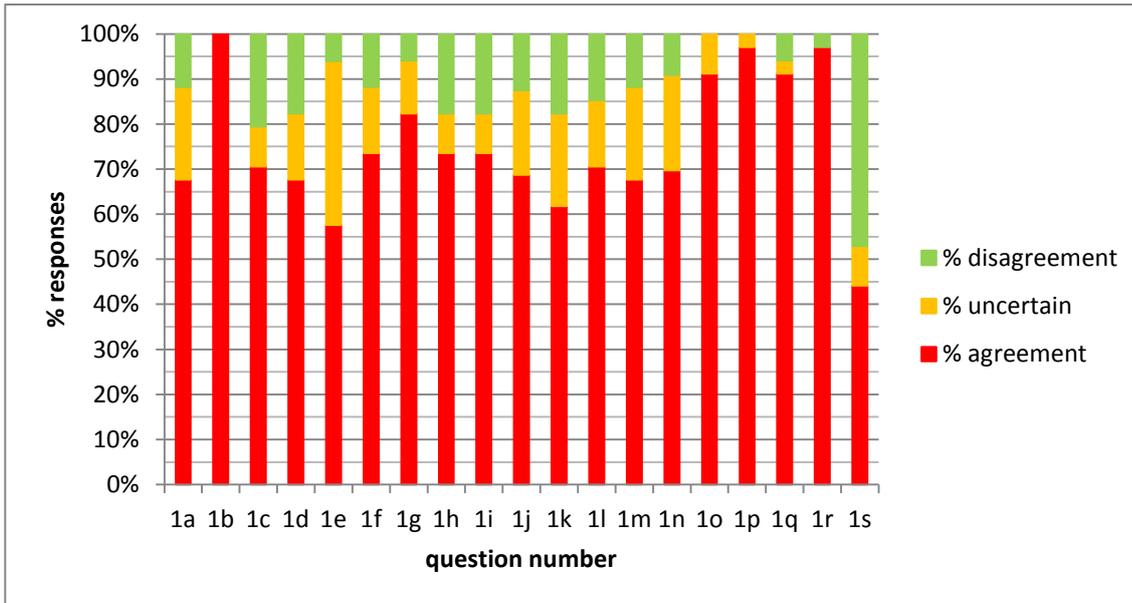
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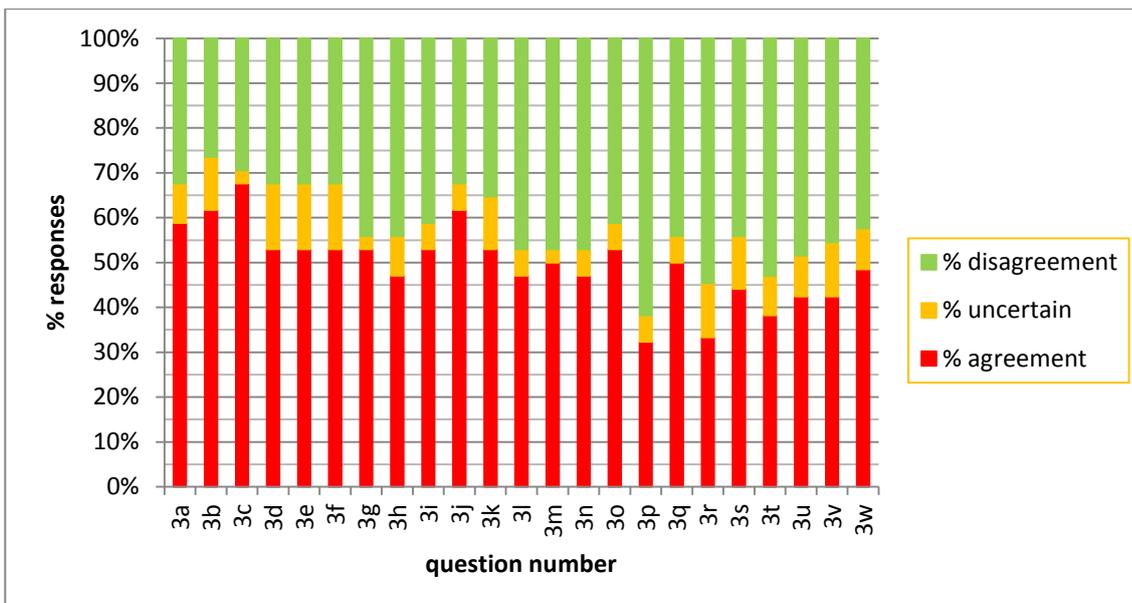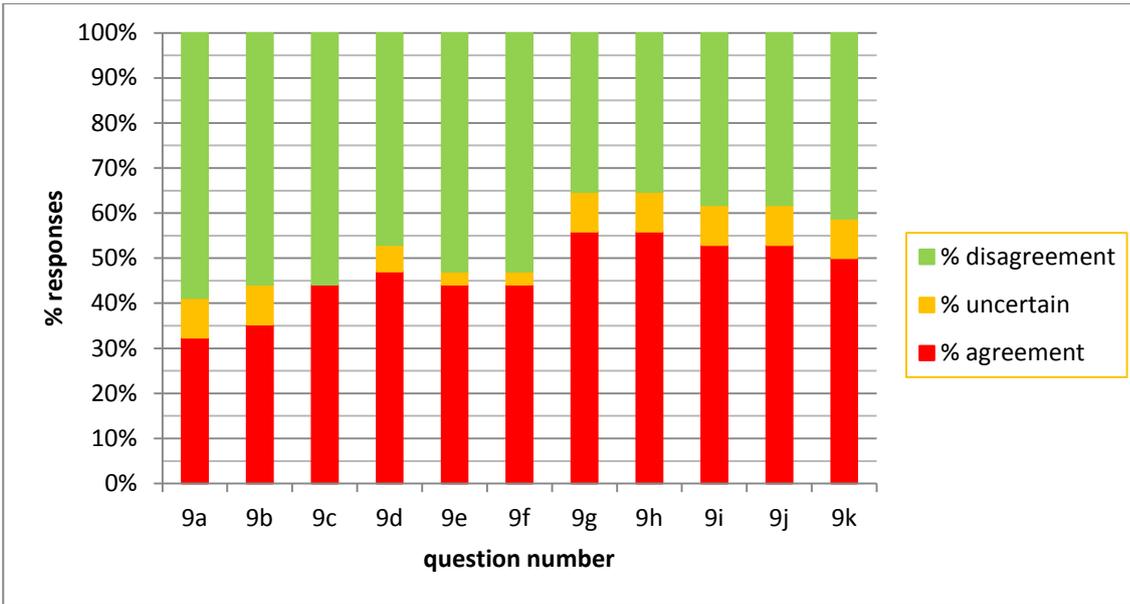

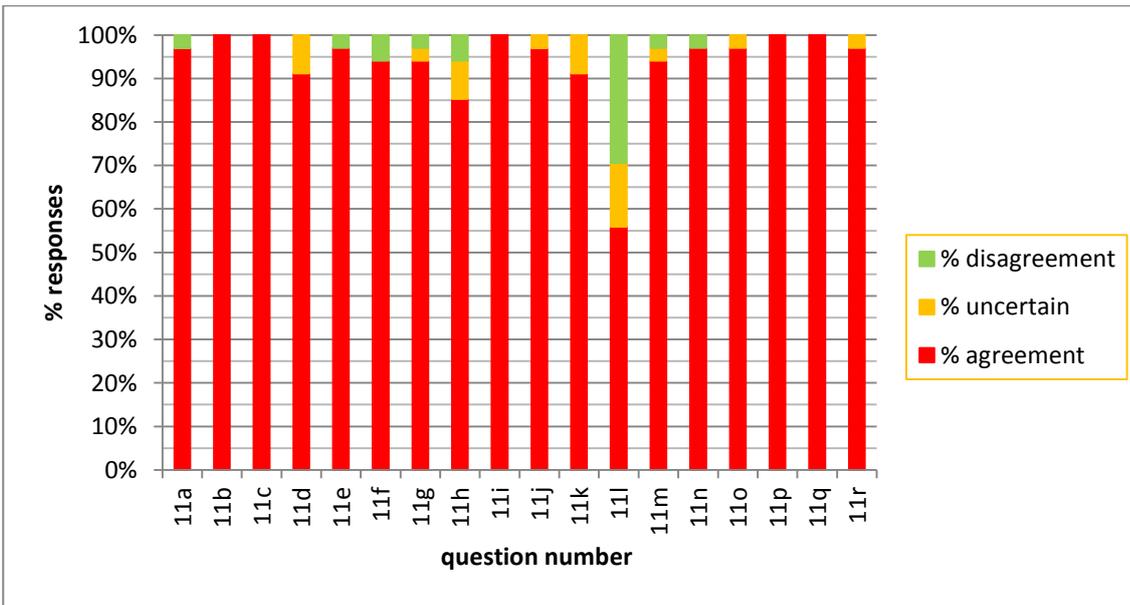*Category 2 – Activities post funding decision but before the study starts*
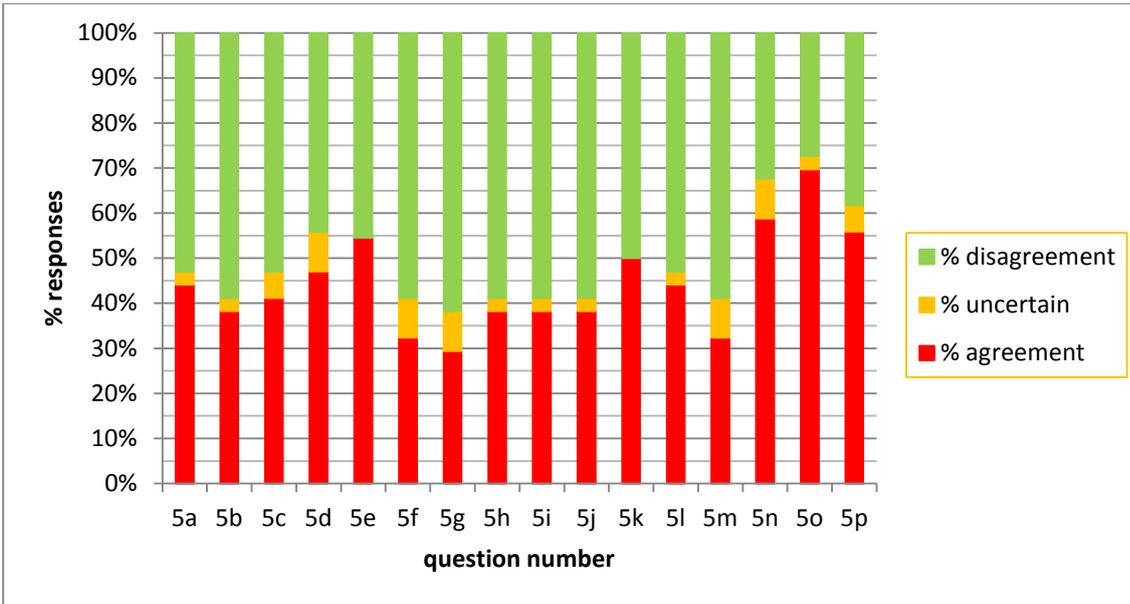
Category 3 – Activities during accrual and active follow-up
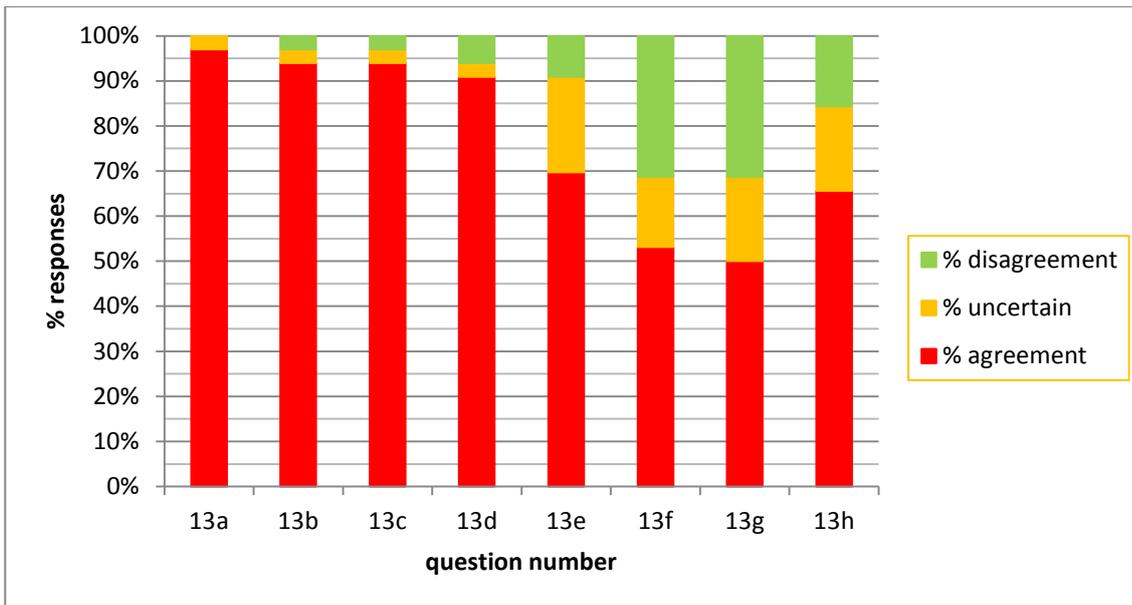

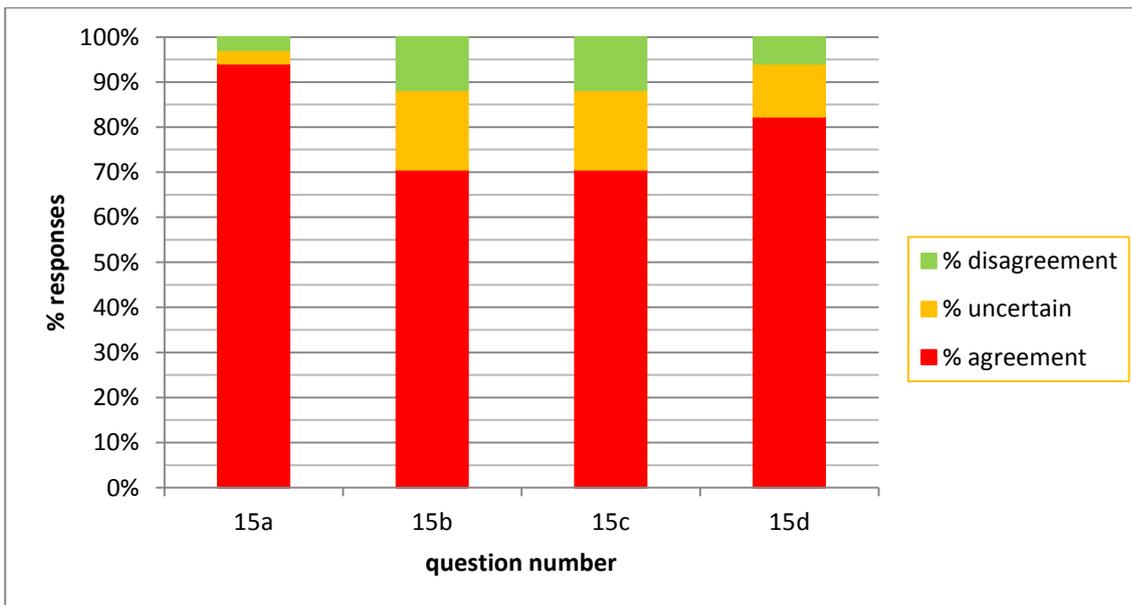*Category 4 – Activities related to data management and analyses*

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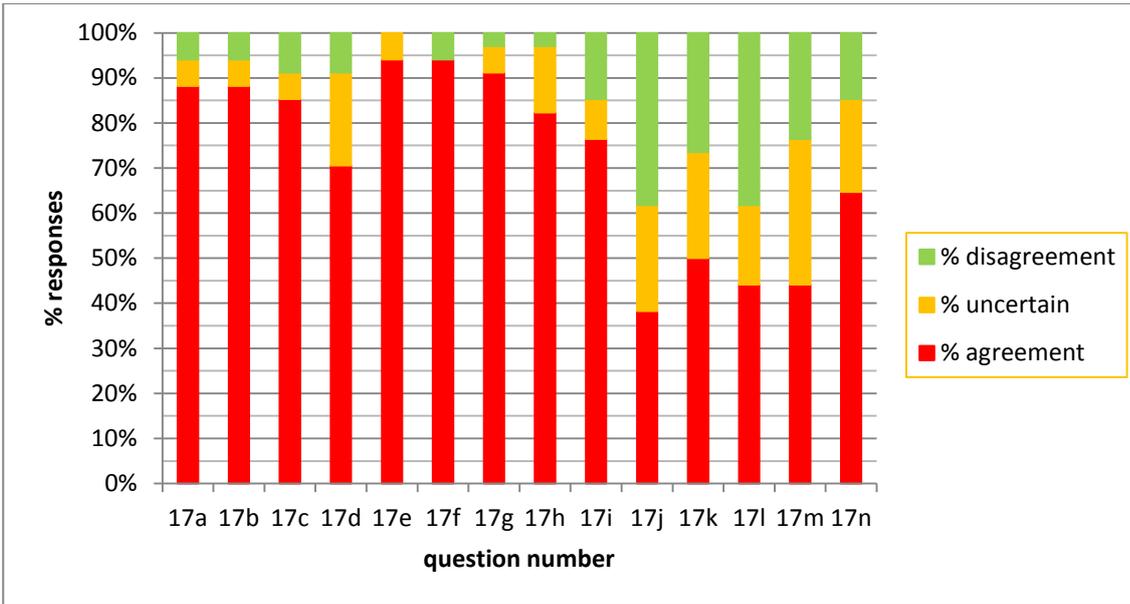

Category 6 – Activities related to general management and strategic development of a CTU

Category 7 – Activities related to training and professional development

Category 8 – Activities related to methodological development

Category 9 – Activities comprising 'national/international contribution'