Chronic Kidney disease Epidemiology Collaboration Clinical Trials (CKD-EPI CT)

Organizational Structure, and Publications, Presentations, and Ancillary Studies Policies

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Section A. Organizational Structure

The CKD Epidemiology Collaboration (CKD-EPI) is a research group with major interests in measurement and estimation of GFR (CKD-EPI GFR)[1-3] and evaluation of surrogate endpoints for clinical trials (CKD-EPI CT)[4-12].

CKD-EPI CT includes analyses of randomized controlled trials (RCTs) and other studies initially collected for the purposes of evaluation of surrogate endpoints. Future analyses may go beyond the evaluation of surrogate endpoints but datasets will be restricted to RCTs (herein referred to as studies).

A1. Organization

Figure 1 shows the organizational chart. CKD-EPI directors are Andrew S Levey, MD and Lesley A Inker, MD MS. The Data Coordinating Center (DCC) for CKD-EPI is at Tufts Medical Center, under the direction of Dr. Inker. The steering committee (SC) for CKD-EPI CT will guide the overall direction and policies, specifically for the work on surrogate endpoints, and will be chaired by Dr. Inker. The statistical center (StC) is at the University of Utah under the direction of Tom Greene, PhD. RCT Recruitment Center (RRC) is at the University of Groningen under the direction of Hiddo L. Heerspink, PhD.

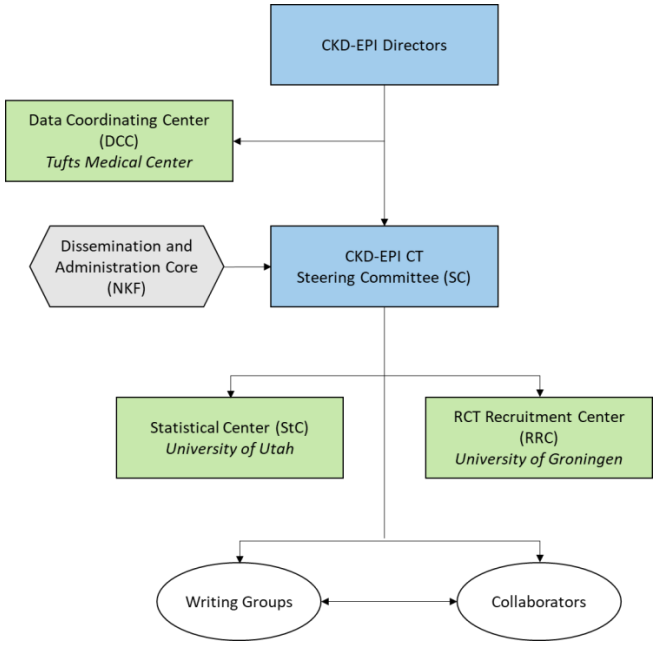

Figure 1: Organizational Diagram

A2. Studies included in CKD-EPI CT and methods of analyzing individual studies

CKD-EPI CT studies have been identified through systematic searches repeated at regular intervals. The ongoing goal is to include additional RCTs on a rolling basis as they become available, with studies identified through updating the systematic searches. Key inclusion criteria are quantifiable measurements of albuminuria or proteinuria, or

serum creatinine to estimate GFR at baseline, measurements of serum creatinine in follow-up to estimate GFR decline and information on end-stage kidney disease (ESKD) incidence thereafter. The number of ESKD events required varies by disease. Our previous publications describe the process of the literature search and study identification and acquisition in detail.[5,6,11,15,16]

We acquire access to studies through different mechanisms. In the first mechanism, data are shared with us by academic institutions or companies that own data sharing rights for the study. Each such study has a primary collaborator who serves as the point of communication to other collaborators or the individual study steering committee. Collaborators are able to opt-in or opt-out of all analyses and publications based on the availability of their study data for the analyses and the willingness of the collaborators to contribute. The second mechanism is wherein we access data from public data sharing platforms. In such cases, we do not designate a collaborator for the study but acknowledge the platform as per the policy of each such platform.

We encourage cohorts to send de-identified individual participant level data to the DCC and StC as this improves flexibility of analyses. As a second option, we are able to analyze the code on a shared server but this method is time inefficient and slows down the process especially if required to perform across many studies, and might incur costs over time depending upon the data sharing platform, which if prohibitive, might prevent study inclusion. As a third option, we can send statistical codes to be run by analysts for the individual studies at their institutions. These codes are complex and performing analyses using this third option will involve time for training and troubleshooting. This adds burden to the analytical team handling the study data and will limit flexibility of refining and updating the analyses.

A3. Roles and responsibilities

The roles and responsibilities of the different branches of the CKD-EPI CT organization are as follows:

Steering committee:

- Overall responsibility for the direction of CKD-EPI CT
- Identify and secure funding
- Determine topics for analyses. Analyses will be rolled out in phases, where each phase identifies one or more papers that can be completed over a 12-18-month period.
- Review ancillary study requests from other investigators
- Review other requests from industry or individuals for specific analyses to be done
- Assign writing group members
- Membership:
    - The SC will consistent of permanent members, one representative of CKD Prognosis Consortium (CKD-PC), and 3-4 rotating members.
    - Permanent members are the CKD-EPI CT leadership. At present these are Drs. Inker, Greene, Heerspink and Levey.
    - The CKD-PC representative will be decided upon by CKD-PC.

  - Rotating members will consist of collaborators, representatives from industry, regulatory agencies, thought leaders or methods experts in this scientific field, or other organizations involved in the analytical questions.
  - Representatives from the industry will be determined based on the following considerations
    - Sponsorship and sharing of individual patient data
    - No data sharing but substantial sponsorship
    - No sponsorship but sharing of data for key studies

Data Coordinating Center

- Conduct systematic literature searches, communicate with collaborators to identify studies, secure data use agreements, transmit data, manage data
- Analyze pooled datasets
- Coordinate manuscript writing
- Keep track of volunteering investigators and those investigators submitting proposals for all ancillary studies

Statistical Center

- Develop methods for new analyses
- Establish QC methods for new and established methods
- Advise DCC on analyses
- Coordinate communication of methods for publications and result presentations and address any related questions
- Coordinate any power or sample size related questions

RCT Recruitment Center

- Coordinate efforts with DCC to engage with potential volunteering investigators and gain access to study data

Collaborators

- Academic collaborators are academic investigators who assist the DCC in acquiring the study data or access to the data. They serve as a point of communication to other collaborators or the individual study steering committee. They will also be part of the writing committee for manuscripts emanating from the analyses.
- Industry collaborators are industry representatives who assist the DCC in acquiring study data or access to the data. They serve as point of contacts to the other collaborators or the company's steering committee for such analyses

Sponsors

- Provide financial support to CKD-EPI CT through the NKF for the main analyses.
- Have a right to request industry sponsored ancillary analyses with additional support
- After signing confidentiality agreement, have the right to obtain preliminary analyses as described in Section C1

National Kidney Foundation

- Administrative core of CKD-EPI CT
- With the support of the DCC, responsible for raising, collecting from sponsors and distributing funds to the DCC, StC and RRC

Section B. Selection of Topics for Analyses

B1. Main topics

The steering committee will vet main topics based on scientific interest, results of survey of collaborators for priority topics, and other factors. These can be divided into primary and secondary topics.

B2. Ancillary topics

The SC will consider two types of ancillary topics:

Ancillary topics proposed by academic investigators (referred to here on in as 'academic sponsored ancillary'): These include topics proposed by academic collaborators for the use of CKD-EPI CT data. The analyses require additional funding to the DCC to perform analyses. The role of the SC will be to consider the scientific merits of the proposal, to determine the nature of the StC input required, to ensure that the DCC and StC have adequate time to perform the analyses without detracting from the main analyses, and that a robust publication plan has been considered. If the SC determines that these criteria have been met, the proposal will be forwarded to the StC for their review and comments. If the SC does not determine the proposal has merit, it will not be forwarded for StC for review.

Ancillary topics proposed by industry representatives (referred to here on in as 'industry sponsored ancillary'): We also welcome proposals from pharmaceutical companies with specific questions to assist in study design, such as power calculations, event rate estimations, and other questions. Since the goal of this consortium is to translate the methodological investigations of the optimal endpoints to real-world study design, for such analyses that do not lead to publications, we plan to provide summary data with the consortium initially and possibly with the larger community through supplements to relevant publications. Analytical proposals will be developed in collaboration between the company, DCC and StC. Additional funding will be provided to the DCC or StC as required. The role of the SC is to ensure that the DCC and StC have adequate time to perform the analyses without detracting from the main analyses.

All collaborators will have the opportunity to opt in or opt out of every analysis.

A detailed description of the procedure to submit proposals for ancillary studies is given in Section D3 of this document.

Section C: Dissemination of Results, Publications and Presentations Policy

C1. Principles for sharing and dissemination of results and confidentiality

Our overall goal is to provide results from analyses related to both the main and relevant ancillary topics that enable a greater number of trials for CKD progression that are more efficient and less costly than currently exists. Thus, we have developed a robust plan for publication, presentation and other data sharing for both results from the main topics and

relevant ancillary topics. We plan to disseminate the final results to the general public through peer reviewed publications and presentations at scientific conferences. In advance of this, we anticipate sharing the results with Consortium members through several methods which might include those outlined below. For items 1-3, we would request signed confidentiality agreement renewed yearly. This confidentiality agreement must be signed before consortium members can participate in webinars and have access to the shared private website. For items 4, we will follow author criteria as outlined in the publication policy below.

1. Preliminary analyses for internal discussion (including recorded webinars or meetings)
    a. Marked strictly confidential – not to be shared outside this consortium and not appropriate for presentation to regulatory agencies
2. QCed specialized analyses
    a. Can be presented to regulatory agencies
    b. Shared across consortium, but not outside
3. Referenceable online report which is updated periodically that includes
    a. Input data for power calculations
    b. Updates to meta-analyses of treatment effects on each endpoint
    c. Updates of trial level meta-regressions as new studies are added to the data base
    d. Requires extensive resources and agreement by those who provide the data to us; assumes continued funding above current level
4. Referenceable peer reviewed publications and presentations at scientific conferences. We plan to include supplementary tables with summary results where appropriate so that items from 1 to 3 can then be in the public domain.

C2. Authorship – general principles

All publications from the CKD-EPI CT will follow approved authorship formats. Academic collaborators and investigations are invited to be authors, as defined below, whereas industry partners are not, unless under certain circumstances, as defined below. All authors are expected to review all manuscripts. Manuscripts will also be sent for review and comment to the CKD-EPI CT collaborators who are not included in the writing committee, from whom data have been used for the analyses. All authors and collaborators have full access to the results from all analyses.

C3. Formation of writing committees and acknowledgements

Main topics

The DCC will send out a questionnaire inviting volunteers for writing committees for each proposed manuscript. All CKD-EPI CT academic collaborators who contributed data to a specific manuscript may volunteer to participate in the writing committee for each paper. One collaborator per study is eligible to be included in the writing committee for each paper which involves data from that study. Subject to specific journal policies, up to four other collaborators from each study will be listed in the acknowledgements and indexed in PubMed where possible. Industry collaborators will not be included as part of writing committees unless there is a scientific rationale (examples: expertise, key topic area)

and will ideally be discussed during data transfer phase. SC, DCC, StC and RCC members' interest will also be elicited. Writing committees for secondary topics can also include other interested parties, such as statisticians engaged in the research area or investigators with experience in this topic. The DCC will compile the list of volunteering investigators and will review with the SC, which has the final authority on the composition of the writing committee, including the assignment of first and last authors.

Ancillary topics

For academic sponsored ancillary analyses, the writing committee for resulting manuscripts will be composed of the following:

- Investigators proposing the ancillary topics
- CKD-EPI CT academic collaborators
- Members of the DCC, StC and RCC, depending upon the topic and technical resources required.

Investigators proposing the ancillary topic shall be the chair of the writing committee, unless decided otherwise by the SC. Reasons for a change will be discussed with the proposer prior to a decision. The DCC will notify CKD-EPI CT academic collaborators, who may volunteer to participate in the writing committee. The DCC will assign the other members of the writing committee, after discussion with the chair, and based on the volunteers.

If industry sponsored ancillary analyses lead to manuscripts, the writing committee can be composed of the following:

- Any industry collaborators with expertise in the area
- Members of the DCC, StC and RCC, depending upon the topic and technical resources required
- Study collaborators and potentially other investigators or collaborators, depending upon the topic and technical resources required.

A member of the DCC or other academic collaborator, unless decided otherwise by the SC, will be the chair of the writing committee.

A detailed description of the procedure to submit proposals for ancillary studies is given in Section D3 of this document.

Authorship format

Writing committee members will be listed as authors on the front page. In general, our philosophy is that credit should correspond to work and effort into a particular manuscript and the order of authors should reflect that. The base scenario for author order is first author, second author if this has been specified, the DCC members, alphabetical listing of the collaborating trial representatives, alphabetical listing of other members of the SC if appropriate, and the last author, however this will be modified depending on the work contributed. "The Chronic Kidney Disease Epidemiology Collaboration" could be chosen as sole author or as last author.

CKD-EPI CT collaborators are listed in the acknowledgements. Editors of journals/PubMed will be requested to index all collaborators individually.

Acknowledging funding of individual studies

A list of the key grants supporting the data collection in the individual cohorts will be included in manuscripts, either in the main paper or in an appendix.

C4. Manuscript generation and review

The same rules apply to abstracts about main and ancillary topics.

Main papers will be written by the first and last author for each topic, with the methods section drafted by the DCC and StC. The DCC will develop, tables, and figures for review by the first and last author and will work together to finalize a draft for review by the Writing Group.

Papers for ancillary topics will be similar to the main papers but there will be additional responsibility for the overall design and methods of the paper for the principal investigator of the academic sponsored ancillary study. The chair of the writing committee will involve designated StC and/or DCC members in the review of each manuscript emanating from an approved ancillary topic, and ensure their approval of the manuscript before submission to journals. To ensure that this occurs, each manuscript that arises from an ancillary study will need to be sent to the DCC as part of the analytical process. The goal is to ensure that the final manuscript ready to be submitted has input from the DCC and StC investigators.

We request that members of the writing committees review and returned manuscript drafts within the stipulated time recommended for each draft.

C5. Abstract generation and review

The same rules apply to abstracts about main and ancillary topics.

Approved writing committees may submit abstracts to national and international meetings, in accordance with rules governing the meeting.

Completed abstracts will be subject to review by the SC and will be sent to collaborators, from whom data have been used for the analyses, for comment.

Abstracts cannot be submitted for publication without approval of the SC. The goal will be to approve drafts within 1-2 weeks.

C6. Presentations

Use of unpublished meta-analyzed data (including analyzed data of individual studies as a form of forest plots or tables with similar concept) for presentations will be limited and will need prior approval by the SC. Acceptable reasons to present unpublished meta-analyzed data are (1) the use for other scientific workgroups, where gain is mutual to CKD-EPI CT and materials are kept to within the group, (2) Official CKD-EPI CT presentation where showing upcoming progress is important for CKD-EPI CT

funding/continuation, (3) presentation by the writing group of submitted abstract. Reviews/invited talks should focus on materials published or in press. Key presentations of CKD-EPI CT meta-analyzed data will be made available on the CKD-EPI website for use by all collaborators.

C7. Abstract/manuscript submission

Unless otherwise specified and agreed upon, DCC will submit abstracts and manuscripts on behalf of the writing groups.

The corresponding author for all CKD-EPI CT manuscript submissions will be listed as follows:

> Chronic Kidney Disease Epidemiology Collaboration Data Coordinating Center
> Principal Investigator, Lesley Inker, MD, MS
> Division of Nephrology,
> Tufts Medical Center,
> 800 Washington Street, Box 391,
> Boston, MA 02111
> Tel: 617-636-2569
> linker@tuftsmedicalcenter.org

CKD-EPI will pay or reimburse for the submission fees and publication cost of CKD-EPI CT abstracts and manuscripts but not ancillary studies.

Section D. Ancillary Studies Policy

D1. General policy

An ancillary study is a proposal for an investigation using data submitted to the CKD-EPI CT which is not in the original CKD-EPI CT analysis plan.

As described in Section B2, we welcome proposals for ancillary studies from academic investigators and collaborators in CKD-EPI CT and from pharmaceutical companies. Both sets of ancillary studies can enhance the value of CKD-EPI CT and encourage interest of the overall goals. To protect the integrity of CKD-EPI CT and ensure adequate resources, all ancillary studies must be reviewed and approved by the SC before their inception, and all require outside (non-CKD-EPI CT) funding to support coordination and statistical analyses.

D2. Requirements for approval of an ancillary study

The proposal must be in writing using standard scientific investigation format. Before an ancillary study can be approved, it must be shown to have scientific merit and that it will not do any of the following:

1. Interfere with the completion of the main objectives of CKD-EPI CT

2. Adversely affect collaborator cooperation in CKD-EPI CT
3. Create a diversion of study resources (personnel, equipment, or study samples), neither locally nor centrally, and
4. Jeopardize the public image of CKD-EPI CT.

D3. Preparation of request for approval of an ancillary study

Academic sponsored ancillary study

The CKD-EPI CT will utilize a two-step process for reviewing ancillary study proposals. Step 1 involves the submission of a brief description of the ancillary study for "concept approval". Step 2 requires the submission of a more complete technical proposal. Submission materials must be in an electronic format.

Step 1: Letter of Intent
Submit a request for concept approval to the CKD-EPI Steering Committee. Include a brief (2-4 page) description of the proposed ancillary study that specifies:

1. Identification of the principal investigator of the ancillary study
2. Names of definite or possible co-investigators/collaborators, including DCC and StC members
3. Proposed funding sources
4. Objectives/specific aims
5. Scientific merit or rationale of the study
6. Study design
7. Timeline of grant application or analyses as applicable
8. Indication of which studies or group of studies will be requested and methodology for new data collection, if applicable
9. Agreement that all ancillary data (clinical information, laboratory assay results) will be shared with the CKD-EPICT DCC.
10. Agreement to follow CKD-EPI CT publications policy for ancillary topics

Step 2: Full proposal
If concept approval is granted, the SC will invite the Principal Investigator to submit a complete proposal. Approval of the technical proposal is required prior to submission to the funding agency or study initiation. The proposal should be submitted to the SC and should include the items listed below. A grant application can be used for items 11-16.

1. Title
2. Identification of principal investigator of the ancillary study
3. Names of definite or possible co-investigators/collaborators
4. A brief description of the nature of the involvement of DCC and StC members
5. Agreement that all ancillary data (clinical information, laboratory assay results) will be shared with the CKD-EPI CT DCC.
6. Agreement to follow CKD-EPI CT Publications Policy for ancillary topics.
7. Proposed funding sources
8. Budget for data coordination, if applicable.
9. Budget for laboratory coordination, if applicable
10. Budget for statistical analysis.
11. Objectives/specific aims

12. Scientific merit or rationale of the study
13. Study design and hypotheses
14. Methodology for data collection, if applicable
15. Proposed statistical analyses
16. Power calculations
17. Proposed publications including tentative timeline and target journals

Industry sponsored ancillary study

Recognizing the fact that the DCC and the StC are engaged with the industry to ensure scientific merit of proposed topics, we waive the requirement of submitting a letter of intent for industry sponsored ancillary topics. We do still require a proposal to be sent to the SC, including the following items:

1. Title
2. Members of the DCC and StC engaged in the development of the analysis plan
3. Proposed funding source(s)
4. Budget for data coordination, if applicable
5. Budget for laboratory coordination, if applicable
6. Budget for statistical analysis
7. Study objectives
8. Scientific merit or rationale of the study, and hypotheses, if applicable
9. Proposed statistical analyses
10. Proposed publications, if applicable
11. Agreement to share summary results via a method deemed best by DCC and SC (i.e. CKD-EPI website, technical reports or supplement tables in publication).

D4. Review of ancillary study proposals

Proposals will be sent to the SC for review, which may confer with collaborators with expertise on the topic. The SC will approve, reject, or request modification of the ancillary study proposal. The key criteria for approval of proposals are scientific merit and impact on the main CKD-EPI CT goals. If the ancillary study is approved by the SC, the Chair of the SC will write a letter to the principal investigator of the ancillary study indicating approval and support of CKD- EPI CT SC. This letter can be used to document approval and support in submission of grant applications for funding or local IRB approval. If the SC does not provide approval, the proposal will be rejected.

D5. Selection of investigators/collaborators in ancillary studies

If concept approval is indicated by the SC, the DCC will circulate a notice with a request for CKD- EPI CT collaborators in addition to those submitting the proposal, to participate in the ancillary study (opt-in/opt-out procedure), to confirm if they would like to be a part of the writing committee (investigator) and whether they have other comments or suggestions. CKD- EPI CT collaborators must volunteer in writing (electronically) to the SC. The SC shall have final authority on the composition of the ancillary study investigators. The DCC will keep track of volunteering investigators and those investigators submitting proposals for all ancillary studies.

D6. Progress reports

For academic sponsored ancillary studies, the Principal Investigator of the ancillary shall provide a written annual report on the progress of the ancillary study. Based on progress achieved, the SC will recommend approval or disapproval for continuation of the ancillary study. In the case of disapproval, permission to continue the ancillary study may be granted to another co-investigator/collaborator (subject to approval by the funding agency).

For industry sponsored ancillary studies, the DCC shall verbally report to the SC during scheduled meetings.

D7. Analysis of ancillary studies

The investigator of the ancillary study, and if necessary the SC, will consult with the DCC and StC during data analysis to ensure that all study data used in analysis of ancillary study results are consistent with data in the main study database. The individual participant data (IPD) of participating cohorts is provided to the DCC or StC for analysis without permission for transfer to other places. Therefore arrangements will need to be made to fund analysts or access the data at the DCC. The investigator of the ancillary study will receive analyzed results, but not IPD, from the DCC. In special circumstances when the academic sponsored ancillary analyses cannot be performed in-house at the DCC, the DCC and SC can coordinate a mechanism for sharing select IPD with the investigator. This is subject to the strong merit of sharing IPD and to the permission from the original contributors of IPD to CKD-EPI CT.

D8. Dissemination of results including presentations, abstracts and publications from ancillary studies

Publications from ancillary studies shall follow the CKD-EPI Publication Policies related to ancillary topics as listed in Section C. In particular, each manuscript emanating from a given ancillary study will should be sent to the DCC prior to analyses. The goal is to ensure sufficient input from StC and DCC investigators in the analyses and interpretation of the data.

Section E. Policy on Individual Trial Publication

This Scientific Workshop is based on the mutual interest of all trials to participate in collaborative research that will improve our understanding and use of alternative endpoints in trials of kidney disease progression. The CKD-EPI CT encourages the activity of individual trials. The publications from individual trials are beneficial to science and the collaboration as a whole.

In the event that there is future funding for CKD-EPI CT to pursue more investigations on these topics, the experience and expertise of collaborating trials will be helpful when

CKD-EPI CT pursues similar topics. We will use the term “vanguard papers” for such projects which aim to improve and refine future CKD-EPI CT projects.

If authors believe they have developed ideas from CKD-EPI CT work (e.g., study design, statistical code) and deem it appropriate to do so, acknowledgement of the collaboration would be appreciated. The DCC aims to continue to share methods and expertise and respond to requests by individual cohorts as much as possible.

While the consortium generally encourages individual trials publishing, groups forming small multi-trial collaborations may not be beneficial for the consortium. This is particularly the case for topics that are being discussed for a full meta-analysis in the consortium. CKD-EPI CT encourages collaborators thinking to form a small collaboration to consider the possibility to proceed with their projects in the entire consortium whenever possible.

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