



C3: CHORD COUSIN Collaboration Application

C3 is pleased to collaborate with you on development of core outcome sets for trials and routine practice. Please email completed proposal to Amit Garg, MD (C3 Chairperson): amgarg@northwell.edu

Contact Information:

Name, Title, Affiliation, Email

COS Leadership Group:

Please list names and emails of any members who will help lead this effort

1. Disease State:

What is the dermatologic condition on which this proposal is based?

2. Aims:

Please list the overarching aims for the proposed outcomes work

3. Background and Previous Outcomes Work in this Disease State:

- Please briefly describe the rationale/need for evaluation or development of a COS in the proposed disease state
- Please briefly describe work already achieved in the proposed area, if any

4. COS Members:

- Please describe the governance and leadership (steering or executive cmte) of the proposed group.
- How will you engage patient research partners in the proposed project?
- Please list the proposed stakeholder roster and roles (i.e., expert/clinician, patient research partner, industry partner, etc).

5. Support:

- Please describe any funding available for your proposal
- Please describe initial support required from C3 (ie, administrative, methodologic, meeting attendance, networking, funding, etc.), if any
- Please describe your thoughts for existing or potential funding from industry or other sources.

6. Timeline:

- Please list intended timelines to major proposal milestones

7. Methods:

- The support of C3 in preparing and conducting your COS project is conditional upon your agreement to develop the COS according to C3 standards. A collaborating partner from C3's Methods committee will also be assigned to your COS group. Submission of this proposal indicates your group's agreement to this approach.

8. Acknowledgements:

As per C3's [Memorandum of Understanding](#), we will ask COS groups to refer to C3 in publications arising from your proposal. The following statement must be included in the acknowledgements section of all publications to ensure that support from C3 is recognized: "The work was developed in collaboration with C3: CHORD-COUSIN Collaboration." Submission of this proposal indicates your group's agreement to this stipulation.

Sample Proposal

1. Disease State:

Hidradenitis suppurativa

2. Aims:

To achieve international stakeholder consensus on a core set of domains for interventional trials

To evaluate existing measures for each of the domains in the core set

To develop measures for the core domain set as required

To achieve international stakeholder consensus on a core outcome set for interventional trials

3. Background and Previous Work:

Randomized Controlled Trials should have well-defined primary and secondary outcomes to answer questions generated by the main hypotheses. However, reported outcome measures in hidradenitis suppurativa (HS) are numerous and diverse. A recent systematic review found a total of 30 outcome measure instruments in 12 RCTs. This use of a broad range of outcome measures can increase difficulties in interpretation and comparison of results, and may potentially obstruct appropriate evidence synthesis by causing reporting bias. One strategy for dealing with these problems is to develop a Core Outcome Set (COS). A COS is a list of outcomes that are meant as mandatory and should be measured and reported in all clinical trials. The aim of this study is to develop a COS for the management of HS.

To our knowledge, this is a unique project with limited prior work.

4. COS Members:

HS will form a section under C3 known as HISTORIC (Hidradenitis SuppraTiva cORE outcomes set International Collaboration)

HISTORIC will have a steering committee comprised of Amit Garg, John Ingram, Gregor Jemec, Joslyn Kirby, Linnea Thorlacius, Bente Villumsen (patient research partner).

5. Support:

Initial support is request for the following:

- Weekly conference line
- Administration of an e-Delphi exercise for core domains
- Attendance of the steering committee and 15 section members at the annual CHORD meeting for 2 years.

We will apply for industry grants and/or sponsorships to further support our work with the declared aim of contributing finances to support our outcomes work.

6. Timeline:

- 2016-2017: Establish core domain set
- 2017-2023: Establish core measures set