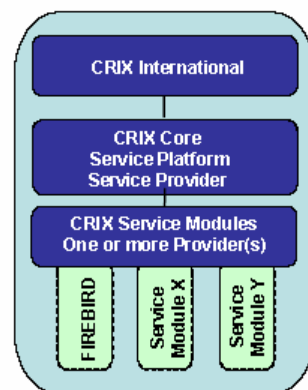


CRIX International: North America Advisory Council (NAAC) Charter

Background

CRIX (which stands for the Clinical Research Information eXchange) is a collaborative community of public and private clinical research stakeholders dedicated to the definition, formation, and ultimate use of an information exchange for clinical and regulatory information.

CRIX International was formed in December 2006 as a not-for-profit entity with the vision of providing a secure, shared-technology, standards-based service platform along with value-added services.



The CRIX International Vision

CRIX International will offer to its stakeholders services aimed at lowering drug development costs and speeding safe and effective treatments to market. More specifically, CRIX will provide the following stakeholder benefits:

- Accelerate and streamline interaction between and among organizations and regulators worldwide involved in drug development (the CRIX Community).
- Simplify the clinical research process burden for investigators, research centers, healthcare providers and patients
- Streamline and enhance global regulatory filing and workflow efficiencies
- Minimize redundant data submission and storage
- Provide a Global Investigator Registry for commonly used/referenced data
- Facilitate the implementation of information exchange standards
- Provide a mechanism for secure, efficient information exchange of research data
- Ensure input, access, and usability to all segments of stakeholder populations

Mission of North America Advisory Council (NAAC)

The North America Advisory Council (NAAC) is one of three Regional Advisory Councils being formed to provide feedback, expertise, and advice to the CRIX International Board of Directors to ensure success and sustainability of CRIX International.

The mission of the NAAC (as well as other Regional Advisory Councils) is to help fulfill the promise of CRIX by enabling marketplace and knowledge expertise and stakeholder input into the conceptualization, planning, and execution of CRIX International initiatives.

NAAC Responsibilities

The key NAAC responsibilities include:

- Establishment of a separate charter, to be approved by the Board of Directors
- Input into CRIX International tactical and strategic plans

- Provision of performance feedback
- Guidance on technology and architecture standards
- Guidance on incubation approach
- Suggestions for service quality improvements
- Assessment of geographic and population-specific needs
- Coordination with other Regional Advisory Councils and the CRIX International Board of Directors to enhance cross-community, cross-cultural communication and minimize duplication of efforts

NAAC Establishment

The CRIX Board of Directors is establishing the NAAC to service the needs of the North American CRIX Community. The NAAC activities will commence on or before April 30, 2007.

The NAAC will continue in operation until the CRIX International Board of Directors deems that the NAAC is no longer needed.

NAAC Composition

The NAAC composition will be reflective of the CRIX Community, which encompasses a broad range of stakeholders as well as geography. Represented within the CRIX community are all organizations involved in, supporting, and/or overseeing clinical research. This includes hospital groups, patient advocates, academic research centers, trade and standards-setting organizations, technical and policy experts and industry service providers, and others.

The NAAC shall have up to twenty-three (23) members who will serve up to five (5) one-year renewable terms.

The NAAC will be comprised of private industry stakeholders, government representatives, and public members. Composition for NAAC is as follows:

- Up to **seven (7)** private industry stakeholder representatives including at least two (2) from small to mid-sized bio-pharma and at least one (1) from Canada and one (1) from Mexico.
- Up to four (4) academic research center representatives including at least one (1) from Canada or Mexico;
- At least (2) investigators from a small or community-based, non-profit health care providers, at least one of which is a minority-serving provider or a community-based provider in a medically underserved area.
- Up to two (2) representatives from contract research organizations;
- At least (2) management, technical, and/or policy experts;
- Up to two (2) representations from the standards community;

- At least two (4) patient advocacy representatives, with at least one from Canada and one from Mexico .

The NAAC will have both a Chair and Vice-Chair. The initial Chair of the NAAC will be appointed by the CRIX International Board of Directors. After the initial year of operation, both the Chair and Vice-Chair will be selected from among and by the NAAC members.

All NAAC members are appointed by the Chair of the NAAC, in conjunction with the Board of Directors nominating committee. NAAC appointments may also be made by the Board of Directors through the nominating committee.

NAAC members will be appointed for a period of one year. Term limits will be imposed to restrict any individual from serving more than five (5) consecutive one-year terms as a member, with the intention to stagger the terms for program continuity.

NAAC members are eligible to be elected as voting members of the Board of Directors.

Former members may be considered for re-appointment after two (2) years of inactivity. NAAC members may be removed at any time for any reason by the NAAC Chair or any Board of Director member. Any individual appointed to the NAAC as a stakeholder representative will step down from their position in the event that their business affiliation no longer reflects that stakeholder interest.

The NAAC Chair reports to the CRIX International Board of Directors. Standing and ad hoc subcommittees will be formed as needed. Subcommittees will be chaired by an existing NAAC member and will report back to the NAAC Chair on a regular basis as needed.

Responsibilities of the NAAC members

It is critical that all NAAC members participate and contribute to monthly teleconferences and annual face-to-face meetings, as well as provide timely reviews of NAAC-prepared documents.

The NAAC Chair will:

- Populate the various NAAC subcommittees with pertinent subject matter experts that are aligned with the mission of CRIX International and the NAAC
- Recruit NAAC members
- Prepare the annual NAAC program plan and budget
- Track discussions on mailing lists and respond appropriately, as a commitment to public accountability
- Draft the Charter for NAAC and obtain approval from the Board of Directors
- Coordination with other Regional Advisory Councils and the CRIX International Board to enhance cross-community, cross-cultural communication and minimize duplication of efforts
- Plan face-to-face meetings and teleconferences
- Review and approve posting of all NAAC-generated documents to public web sites

A CRIX International-supplied administrator or a volunteer participant on the NAAC will serve as the Team Administrator and ensure that:

- Post the agendas for upcoming face-to-face meetings and teleconferences
- Record and post minutes of face-to-face meetings and teleconferences
- Maintain and make available documents actively under consideration by the NAAC
- Ensure NAAC member (private) and non-member (public) mailing lists and web pages are adequately maintained

Communication Mechanisms

Face-to-face meetings: The NAAC in-person meetings will be held annually and scheduled, when possible, in conjunction with Board of Directors meetings to achieve optimal exchange and communication. Meeting details will be made available on the NAAC web page.

Teleconferences: Monthly one-hour phone conferences will be scheduled. In addition, there may be ad hoc meetings called as necessary. The exact details, dates, and times, as well as the agenda will be published in advance on the NAAC web page, and notification of upcoming teleconferences will be provided via the NAAC-members group mailing list.

Mailing Lists: The NAAC-member-only mailing list is the primary means of electronic discussion within the NAAC. There will also be an archived NAAC-public mailing list used for public discussion of NAAC activities, documents, etc.

NAAC Web Page: The NAAC shall maintain a web page on the CRIX International web site that shows the list of active documents, schedule of meetings, and links to email archives, meeting minutes, and the list of Advisory Council participants etc.

Voting Mechanisms

The NAAC works by consensus. In the event of failure to achieve consensus on substantive issues, the group may resort to a vote. Each Member in good standing may vote. There is one vote per Member.

Where verbal consensus is not reached during a meeting or teleconference, votes may be held by email to allow all participants a chance to vote. For these, there is a two-week voting period followed by a period of two working days for the announcement of the result. In the event of a tie, the Chair has the deciding vote.

Resources Required

The NAAC will execute their mission by relying on guidance from the Board of Directors. Any logistics requirements will be supplied through the CRIX International Management and Operational Delivery Organization.

Face-to-face meetings are generally hosted by organizations participating in the NAAC. This will involve arranging a place to meet, reserving accommodations for participants, and catering, so as to maximize effective working time. Reimbursement for travel, accommodations, and per diem will be provided to those NAAC members from non-profit organizations.

Confidentiality of CRIX International Information

At times there may be a need to share confidential financial or other information regarding CRIX International activities. NAAC members agree to hold in confidence and not to disclose information clearly identified as confidential to outside parties and not already in the public domain.