NCATS Accrual for Clinical Trials (ACT)

Governance

ABSTRACT

The goal of the ACT project is to create a federated network of sites from the National Clinical and Translational Science Award (CTSA) Consortium to significantly increase participant accrual to the nation's highest priority clinical trials. To achieve this goal, we will leverage the widespread implementation of the electronic health record (EHR) and the well-established extensive informatics and regulatory expertise within the CTSA Consortium.

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1. Terms, Definitions and Local ACT Functions

ACT Data Steward / User Liaison: Designee(s) of an ACT Network Site with auditing and monitoring responsibility of the local ACT Site – including data quality and conformance to Terms of Query Access Policy. The Data Steward / User Liaison serves as the main point of contact for the site user.

ACT Executive Committee: Formed by the ACT PI leads, one lead from each Work Group (Governance, Regulatory, Technology, Dissemination & Evaluation and Data Harmonization) and a member of NCATS leadership.

ACT Functions: Functions integral to the implementation, maintenance, and participation in the ACT Network. Details are found in Appendix A.

ACT Network Operations Procedures: This document is designed to describe the technical structures, responsibilities and operational processes for participating ACT sites and ACT Network Operations. It can be found here.

ACT Network Site: An institutional member of the ACT network; one who has signed the ACT Network Site Agreement.

ACT Network Site Agreement: Agreement signed by each institutional member of the ACT Network. Includes policies and procedures the site must follow to participate in the ACT Network.

ACT Network Stage: The NCATS ACT Project has two stages. Stage 1 launched the cohort discovery tool to 21 CTSA hub from 2014-2017. Stage 2, from 2017-2021, will bring on board up to 13 additional CTSA hubs annually, and by the end of 2021, will allow for the identification of patients and will facilitate study enrollment.

ACT Network Qualified User: A person with authority to query the ACT network per the ACT Network Site Agreement and the Terms of Query Access.

> **ACT Qualified Faculty:** A faculty appointee of an ACT Network Site that fits the following criteria: 1) At or above Instructor level (Clinical and Research Fellows or doctoral students will be able to access cohort counts as approved by the Fellow's or student's designated faculty mentor) and 2) Either primarily appointed by, contractually related to, or on the medical staff of a participating ACT Network Site or partner institution. ACT Qualified Faculty oversee supervised Fellows and other Qualified staff in their access of the network.
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> **ACT Qualified Staff:** A person who has been approved by an ACT Qualified Faculty member to access the ACT Network. All queries conducted by Qualified Staff are ultimately the responsibility of the ACT Qualified Faculty.

ACT Terms of Data Use: The terminology that defines the processes and policies surrounding potential study participant data used for the purpose of recruiting participants into the nation's highest priority clinical trials.

ACT Work Groups and sub-committees: Per the NCATS supported ACT administrative supplement notice of award, there are five Work Groups: Dissemination & Evaluation, Governance, Regulatory, Technology, and Data Harmonization. Each Work Group has a lead or co-leads authorized to create sub-committees as needed for specific tasks and for the creation of work products. Additional Work Groups may be added for Stage 2.

CTSA Hub: The institution that has been awarded an NCATS Clinical and Translational Science Award (CTSA).

Data Concierge / Honest Broker: A local role that is responsible for providing patient identifying information that can be shared with study enrollment teams, as approved by the local IRB.

Dissemination Lead: Assumes overall responsibility for the rollout of ACT to local investigators. Details are found in Appendix A.

EHR: Electronic Health Record. Used in lieu of Electronic Medical Record (EMR) as well.

Hub Operations Coordinator (HOC): Assumes overall responsibility for monitoring the ACT test, staging, and production networks as a member of the Harvard SHRINE team.

i2b2 Plugin: A software module that extends the local functions of an i2b2 instance.

Ontologist: Collaborates with ACT Data Harmonization Work Group and ACT ontology development. Details are found in Appendix A.

Originating Site: The ACT Network Site from which a user makes a query to the ACT Network.

Originating Researcher: Researcher who performs an initial query across the ACT Network that results in either a single or multi-site study.

Patient Identification: For the purposes of this document, *patient identification* refers to the *local site* obtaining participant contact information necessary to recruit a subject to a study in accordance with their local IRB approval. This does not imply any release of patient-level data by external manual or automated means.

PI Group: The four Principal Investigators listed on the NCATS grant – Steven Reis (University of Pittsburgh Medical Center, Gary Firestein University of California San Diego, Robert Toto UT Southwestern Medical Center, Lee Nadler Harvard. The PI Group will review any policies and issues to be managed within the ACT Executive Committee.

Receiving Site: An ACT Network Site that is one of the recipients of a query made from an Originating ACT Network Site.

Research Data Curator: Maps local data to ACT ontology and ensures accuracy and compliance of data available to the ACT Network. Details are found in Appendix A.

Site Lead: Assumes overall responsibility for the site's activities in the ACT Network. Details are found in Appendix A.

Site Operations Coordinator (SOC): The primary site individual responsible for technical operations. This individual works closely with the Data Steward to troubleshoot and resolve site user issues.

Site Researcher: Researcher who is part of a multi-site study that shares ACT generated information with the local data concierge / honest broker service for participant identification.

System Administrator (application and infrastructure): Provides support in installation, implementation, and maintenance of ACT technology frameworks (i2b2 and SHRINE). Details are found in Appendix A.

2. Background

Advancing translational research to improve human health requires that sufficient numbers of patients and patient materials be available for clinical investigations. As scientific knowledge advances, our understanding of the heterogeneity of human illness becomes clearer and therefore the selection of appropriate patients for clinical investigation becomes more challenging. It is therefore critical to ensure that we can identify these patients, provide them with research opportunities, and invite them to join clinical trials. However, the majority of clinical trials are unable to recruit their proposed number of research participants within their planned time frame. Failure to accrue eligible patients in trials is inefficient, wasteful, limits generalizability of results, and can lead to premature closure of trials before completion.

The Electronic Health Records (EHR) that are used clinically at nearly all academic medical centers provide an opportunity to significantly increase the efficiency of clinical trials by identifying eligible patients based on demographic, diagnostic, procedural, lab, pharmacy, billing, and other data. However, the use of EHRs to enable patient accrual to multi-site trials is severely limited because EHRs do not use a common ontology and are not linked across multiple institutions. There are also important privacy and regulatory concerns that need to be addressed in order to use the EHRs cooperatively.

A major strength of the NCATS Clinical and Translational Science Award (CTSA) program is its networking of academic medical centers across the nation. This was recognized by the Institute of Medicine's report of its objective evaluation of the CTSA program, which stated that the CTSA program should "…establish a national network that will accelerate the development of new diagnostics, therapeutics, and preventive interventions and, at the same time, drive innovation in clinical and translational research methods, processes, tools, and resources." (*Institute of Medicine. The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research*. Washington, D.C.: The National Academies Press; 2013). Many individual CTSAs are capable of identifying and engaging local patients for clinical trials and research studies through their EHR. The goal for the CTSA consortium is to develop the informatics tools, regulatory infrastructure, and governance structures that are required to leverage the EHR across CTSA sites and thereby across the nation. By achieving this goal, we will have a significant impact on clinical and translational research across America, positioning ourselves to be a leading site for clinical trials by biotechnology and pharmaceutical companies.

3. Accrual for Clinical Trials (ACT) Proposal

The goal of ACT is to implement CTSA-developed informatics infrastructure across waves of CTSA sites and apply existing best practices to increase patient accrual to clinical trials. This network of sites will be called the NCATS ACT Network. The first wave of NCATS ACT Network Sites will establish a functioning network and develop the initial policies and procedures that govern identification of study participant cohorts across multiple sites. Once established and implemented, this federated network will become an engine for efficient, safe and lower cost multi-site clinical trials and translational research studies for all CTSAs. It will arguably be an unprecedented national resource. Achieving this goal will substantially reduce and eventually eliminate a major barrier to conducting the highest priority clinical trials.

The purpose of this document is to outline the governance principles and procedures to be used by ACT in its administrative functions.

ACT has four Specific Aims and five years between 2017 – 2021 to accomplish its goals:

- *Aim 1* will launch the ACT nationwide cohort discovery tool and assess study accrual feasibility at the 21 ACT CTSA hubs for multisite clinical trials.
- *Aim 2* will create the world's largest network for cohort discovery.
- *Aim 3* will enable identification of potential research subjects for clinical trials among all ACT network participants across the CTSA consortium.
- *Aim 4* will facilitate clinical trials sponsored by investigators, foundations, the NIH and industry.

An evaluation process to monitor the progress, successful completion as well as sustainability of ACT is in place and will be ongoing.

4. Governance Document

This document is designed to enable future amendments in order to include additional stakeholders, sponsors, and other items described herein. Each ACT Network Site will collaborate with other institutions within the ACT Network to develop the informatics tools and regulatory infrastructure that are required to leverage the EHR across CTSA sites nationwide. Each site will lend its expertise in the utilization of their EHR, informatics infrastructure and regulatory expertise to navigate their

institutional policies and procedures to launch the ACT Network and conduct cohort exploration studies serving the NIH Institutes and Centers and Industry sponsored research.

5. Governance Principles

Governance includes the processes we define and use to make key decisions on how ACT will operate, accomplish strategic goals, and optimally deploy resources. The purpose of governance is to support ACT as it works to achieve its goals and aims. Organizationally, and particularly in Academic Health Center settings, there is often a strong desire for comprehensive and highly formal governance, but this can also undermine organizational agility. ACT governance attempts to strike a balance between ensuring an equitable decision-making process that facilitates consensus seeking while minimizing unnecessary bureaucracy. Our governing principles are as follows:

- Strive for a balanced governance that encourages open discussion and transparency
- Implement a structured, thoughtful and comprehensive governance while minimizing bureaucracy
- Ensure appropriate representation that encourages consensus-seeking

6. Governance Scope

Governance is an essential component of decision-making in a consortium and enabling progress towards goals and objectives. Important aspects of governance include:

- WHAT types of decisions are covered by the governance entity or entities
- WHO will be involved
- HOW will decisions be made
- WHEN and WHERE decisions will be made
- FINANCIAL CLARITY regarding allocations, authority and accountability

The scope of ACT requires each *site* to collaborate with other institutions within the CTSA consortium to develop the informatics tools and regulatory infrastructure required to leverage the EHR across *CTSA hubs* nationwide. Each *site* will lend its expertise in the utilization of their EHR, informatics infrastructure and regulatory expertise to navigate their institutional policies and procedures to launch the ACT Network and conduct cohort exploration studies serving the NIH Institutes, Centers and the member institutions. By participating, the member Institutions of ACT concede oversight and management of the ACT program to the ACT Executive Committee.

7. Governance Structure

The governance structure developed for ACT includes required reporting to NCATS through the ACT Executive Committee, an entity providing executive oversight for the project. It is outlined in Figure 1, below.

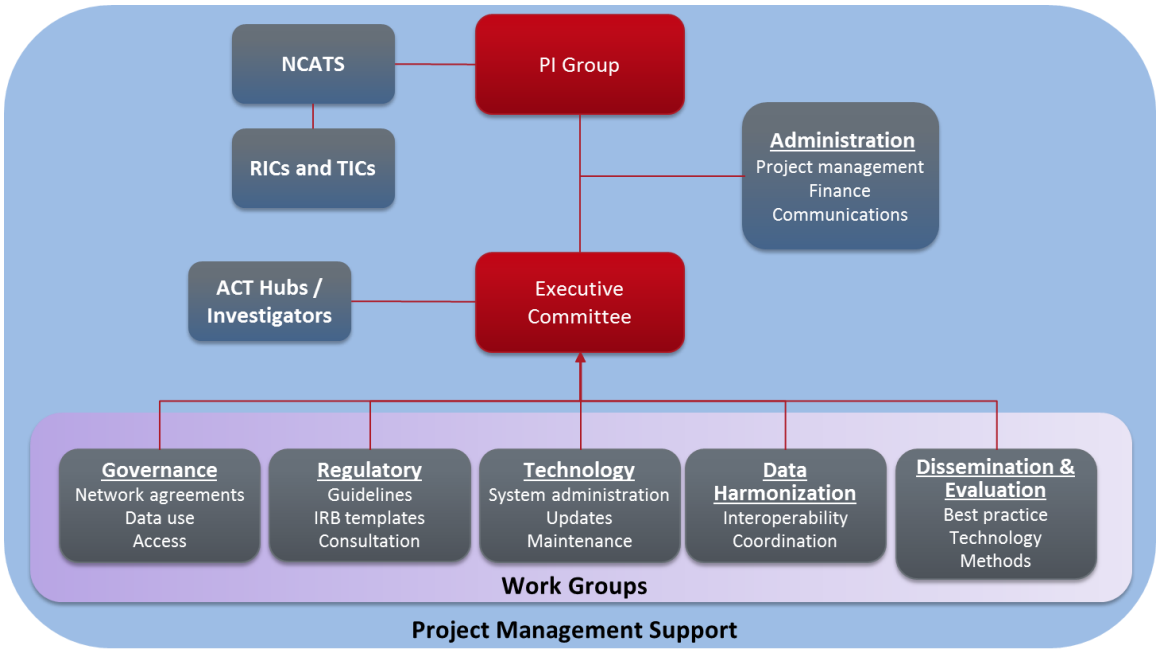


Figure 1. ACT Project Governance.

ACT Governance Elements include:

1. PI Group
2. ACT Executive Committee
3. ACT Work Groups and sub-committees

PI Group: Formed by the ACT PI leads, this group is ultimately responsible for the overall performance and strategy for ACT. As such, the PI group has the authority to adjudicate decisions and issues.

ACT Executive Committee: Formed by the ACT PI leads, Work Groups leads (Governance, Regulatory, Technology, Dissemination & Evaluation and Data Harmonization) and a member of NCATS leadership. The goal of this committee is to make most or all decisions by consensus and/or voting for ACT. It decides on the priorities and deliverables for each ACT Work Group. An NCATS ACT principal investigator will be appointed to serve as the committee chairman.

ACT Work Groups and sub-committees: Per the ACT contract, there are five Work Groups: Governance, Regulatory, Technology, Dissemination & Evaluation and Data Harmonization. Each Work Group has a lead or co-leads that serve(s) on the ACT Executive Committee and may create sub-committees as needed for specific tasks and for the creation of work products. Each Work Group reports to the Executive Committee and each Work Group has an appointed PI liaison as an ex officio (non-voting) member. The Executive Committee can sunset Work Groups and create new Work Groups to support the project as ACT evolves. Work Group membership varies and is defined by the Work Group Leads. Membership is either open to anyone who is interested in participating, or membership is extended to individuals voted upon from across the ACT community. Membership is evaluated annually and is likely to change.

- **Governance** – responsible for network agreements, data use, governance documentation and network access guidance
- **Regulatory** – provides regulatory guidelines, IRB templates and consultation as necessary
- **Technology** – supports system administration, technology upgrades / updates and system maintenance, informatics community building and strategic technical planning.
- **Data Harmonization** – oversees data harmonization, the ACT ontology, interoperability, and coordination
- **Dissemination & Evaluation** – responsible for developing training materials and dissemination guidelines for network rollout to investigators; also includes evaluation efforts that will assess

the efficacy of training, communications and the overall functioning of the ACT network

Project Management: There is external project management contracted for the ACT Project to:

- Provide a single point of contact for information, while managing and facilitating all communication, documentation, and reporting across the ACT program.
- Deploy a consistent set of tools and processes to assist the individual site implementations.
- Encourage collaboration, best practices and information sharing across the sites.

8. Voting

The ACT Executive Committee votes on items brought forward by the Work Groups, network operations, and member institutions on an as needed basis. The committee is composed of the following individuals: four principal investigators of the ACT program, Work Group leads, co-leads and additional Work Group designees and an NCATS member appointed by NCATS leadership. Note: Up to two representatives from each Work Group can participate on the executive committee if there are Work Group co-leads, but each Work Group has only one vote. Voting members must either cast a vote or name a delegate to cast a vote. The required quorum is participation by at least five voting members, of different work groups, and including at least two ACT PIs, in any item brought to a vote. To be passed, decisions/resolutions require a simple majority. A voting member may vote in absentia (e.g. email) as needed.

9. Communications

Guidelines are provided for external communications to stakeholders and internal communication – between sites, Work Groups, sub-committees and Executive Committee, and external communication to stakeholders.

- **Use of the ACT name** – The ACT name, NCATS Accrual to Clinical Trials may be used by NCATS and all participating ACT Network Sites. In addition, others may use the ACT name with written prior approval by the ACT Executive Committee. In all communications on behalf of the project and network, refer to the project as NCATS Accrual to Clinical Trials (ACT) or ACT, using the ACT abbreviation after it has been spelled out initially.
- **External Communications**
    - NCATS
        - Communications with NCATS are facilitated by the NCATS appointed member of the ACT Executive Committee.
        - Communications with NCATS are both informal and formal. These communications will also be shared with the ACT Network Sites in order to foster understanding, trust, and confidence.
        - Status updates to NCATS are provided on a quarterly basis.
        - Meetings with NCATS leaders, to discuss project progress, may include invited speakers from the project and from sites, as recommended by NCATS and the ACT Executive Committee. Presentations will be shared with the entire ACT team.
        - Feedback and questions that arise from presentations to NCATS should be recorded by a designated scribe at the meetings. These notes should be made available to the entire ACT team via email and archived in a secure area of the ACT national web site (see below).
    - Potential Sites - Project status and information regarding participation in the network should be provided to potential sites by the ACT Executive Committee, as prepared by its Work Groups. Material should be made available online, as well as document format (PDF) for emailing as attachment. The following are principles governing communications with potential sites:
        - Transparent communications are critical, especially regarding inclusion criteria and selection process for participation in Waves of CTSA hubs.

        - Inquiries from potential sites must be managed by the Executive Committee.
    - The Public - ACT maintains a document management site and a national website, clearly identified as NCATS Accrual to Clinical Trials. A monthly newsletter is also distributed to the ACT community and others who express interest in receiving it. The communication channels provide the following forms, documents and checklists:
        - Governance documents
        - Requirements for participating in ACT
        - Policies and procedures for queries
        - Standard Operating Procedures for ACT
        - Usage Metrics
        - Progress Reports
        - End user training materials and general network guidance
        - ACT work products such as data harmonization.
        - Media - All inquiries from the media should be referred to NCATS communications specialists.
- **Internal Communications**
    - Principles
        - The work of parts of the team (Work Group, Committee) must be visible to the entire team through the national website or designated document repository tool.
        - Promote transparency and open communications. That is, the work of each team member must be visible to the entire team.
        - Promote continuity. There will be a transition from Work Group centric activity to site centric activity. As the network is defined, we will move from predominantly Work Group communications towards network-focused communications regarding site status and the needs of the network as a whole.
    - Characteristics
        - Dissemination of decisions, status updates
        - Key project information such as schedules, budget, risks, modifications
        - Transparency of meeting schedules
        - Freedom for ad hoc meetings/calls as Work Groups require
        - Site-specific numbers of records, years covered, date of last refresh, etc.
- **Contact List** - The ACT web site must contain an up-to-date contact list for all active ACT team members. Contact information should be readily accessible from web site search and via web site home page link. A designated ACT team member should maintain this information.
    - Contact information for each person should include:
        - Name
        - Institution/Site
        - Email address
        - Phone
        - Committee/Work Group(s) and role (e.g., Governance Work Group, Communications sub-committee lead)
- **Standard communication language for participants**: ACT sites will agree to use (or base their own communications) on standard language that can be used with participants regarding such issues as disclosure, transparency, security, protection of data, no sale of data to industry, etc.

10. ACT Network Site Responsibilities

The decision to participate in a study is left to the ACT Network Site authority. There is no obligation for a site to participate in a study proposed by another ACT Network Site.

It is not the responsibility of the Data Steward or the Site Operations Coordinator to identify a site PI for a proposed study.

Additional ACT Network Site Responsibilities are found in the ACT Network Operations Procedures document.

All institutions desiring to participate in the ACT Network must agree to the following:

- ACT Network Sites hold active NCATS-funded CTSAs or are affiliate health systems of an NCATS-funded CTSA.
- ACT Network Sites will join in waves over time. Criteria used to demonstrate readiness include:
    - Support and commitment from institutional leadership to achieve the goals of the ACT project,
    - Installation of i2b2 and SHRINE software,
    - Performance of regular data updates from the site EHR to the site i2b2,
    - Dedicated informatics staff to support software and informatics systems and upgrades,
    - A patient population that will contribute to diversity across the network
    - Previous experience participating in networks will also facilitate participation in ACT.
- The ACT Network Site CTSA PI will nominate a faculty representative to lead the ACT project locally, who will serve as the ACT Site Lead and have the authority and resources to appoint faculty and staff to participate in working groups and serve on committees. These representatives will possess appropriate experience, authority and knowledge to assist in establishing best practices.
- ACT Network sites will conduct example queries as needed to demonstrate the functionality of the ACT Network and will provide aggregate counts of patients meeting designated criteria.
- ACT Network Sites will only provide a summary data count in response to a query in the first two Aims of the ACT project. Participant identification, encompassed in Aim 3 of the project, may be accomplished with three i2b2 plugins. This technology will only be used for local participant identification by the local data concierge/honest broker upon IRB approval. Identifying information will only be shared with other sites participating in that IRB approved study.
- Once an ACT Network Site's institutional leadership has provided approval of the ACT Network Site Agreement, ACT Network Sites will be permitted to join the network hub.
- Upon their technical rollout, ACT Network Sites may utilize the i2b2 plugins for participant identification once a study has secured IRB approval. The use of i2b2 plugins is at the discretion of the site.
- ACT Network Sites agree to participate in a governance structure that will work collaboratively to develop and adopt policies and procedures for data harmonization, query access, data privacy, communications and dissemination of results, attribution, and management of Conflicts of Interest.
- ACT Network Sites will secure appropriate institutional approval for the sharing of clinical data for research purposes, including approval (if granted) to publish patient counts identified as originating from their institution.
- Insuring Integrity of Data Use:
    - All data queries will be archived and can be included, by request, in reports to the ACT Network Executive Committee.
    - The Local Data Steward will periodically audit individual data queries for compliance with the original intent of the query.
    - The ACT Executive Committee will resolve requests and issues not covered by existing policies and will develop a policy for penalties (and possible exclusion from ACT) that will be applied for violations of these policies.

- Participating sites will be expected to provide data to sites that comprise the network.
- This policy will be reviewed by the NCATS ACT Executive Committee regularly and updated as needed based on feedback from the investigator communities and the leadership of each organization involved. Any updates or changes will require an amendment(s) to the agreement.

- Citations
  - Publications in which data source partners (hospitals) are to be identified by name will be reviewed for use of name only by each identified hospital or health system prior to submission of a manuscript. At no time will specific participating data source partners be named unless explicitly approved by the data partner. Such approval must be requested and received in writing between the requestor and the Senior Vice President of Research, the Chief Information Officer, or their respective designee. Any entity (e.g., hospital) that does not agree to be identified by name as a data source will be instead identified as a "CTSA-affiliated hospital."
  - Publications based on research using the ACT Network should cite the NCATS ACT grant and appropriate CTSA Hub grant numbers from participating organizations. It is the responsibility of the ACT Network Site to provide reminders to ACT Network Users and to monitor to ensure appropriate citing of the grant.
  - Any Intellectual Property derived from use of the ACT Network must cite the NCATS ACT grant.

- Site Technical Service Level Agreements
  - Network uptime will be maintained by participating sites in the following manner (additional information may be found in the ACT Network Operations Procedures document).
    - The Hub Operations Coordinator (HOC) will run routine tests of the network that will check for operational issues. Results of each test will be shared with system administrators and Site Operations Coordinators (SOCs). In the future, network Uptime/Downtime status will be posted on the website.
    - Each site will designate a member of their staff as the Site Operations Coordinator (SOC) who is responsible for local technical operations.
    - The Data Steward will be the main point of contact for local users (users at that institution/site) regarding possible operational and technical access issues. The Data Steward will work with the SOC to troubleshoot and resolve these issues.
    - Scheduled site technology downtime will occur during the weekly downtime window of Tuesday nights (between 4pm EST and Wednesday 7am EST). There may be times when additional downtime is required across the network. These times will be communicated out across the ACT technology distribution list and posted on the ACT website.
    - Locally scheduled downtimes will be communicated by the SOC to all other network SOCs and the HOC at least 24 hours prior to the event. It is required that sites abide by the network downtime window timeframe. Emergency or unplanned downtimes will also be communicated by the SOC to all other network SOCs and the HOC utilizing the ACT technology distribution list as the SOC learns of the issue.
    - Each site's SOC will be responsive to other site SOCs and the HOC regarding possible operational issues at their site.

        - If an operational error is identified at a site, the SOC will coordinate resolution of that error and the process of bringing their site back online. The SOC will notify all SOCs and the HOC, again utilizing the ACT technology distribution list, that the issue is recognized and is being addressed.
    - Network participation will be based on adhering to these uptime agreements and the following site maintenance criteria. Additional information may be found in the ACT Network Operations Procedures document.
        - Each site is expected to refresh their i2b2 data at least monthly, although more frequently is preferred.
        - Software and ontology updates – each ACT Network Site will perform annual updates/upgrades to the i2b2 and SHRINE software and the ACT ontology as guided by the ACT Network Operations group and approved by the ACT Executive Committee.
        - Utilization reporting – each ACT Network Site will provide reporting to the ACT Executive Committee on numbers of users and queries on a regular basis. This process is coordinated among site Data Stewards, the ACT Evaluation team and the national project manager.
        - Feedback from users – each ACT Network Site will agree to survey their users for feedback as determined by the Executive Committee and ACT Dissemination team.

11. ACT Network Site Policies

- All institutions desiring to participate in the ACT Network must agree to and officially sign an ACT Network Site Agreement that incorporates the following principles of participation: ACT Network Sites will secure IRB review and approval for their i2b2/SHRINE participation in the ACT network.

- The ACT Network Sites will implement the Terms of Query Access and Standard Operating Procedures that will permit approved users access to the SHRINE federated query tool for the purpose of requesting aggregate clinical data from participating ACT organizations.

- Insuring Integrity of Data Use:
    - All Qualified Faculty, supervised Fellows, Qualified Staff working under a qualified faculty member and their collaborating investigators must complete and sign the ACT Terms of Query Access before making a data request; this module will contain the following elements:
        - Acknowledgement of principles regarding ethical considerations in using shared clinical data;
        - Statement prohibiting any attempt to identify any individual patient;
        - Appropriate language regarding protection of intellectual property;
        - Publication policy (regarding citation of CTSA Hub grants, use of participating ACT Network Site names, etc.);
        - Statement of penalty for violating agreement as designated by local institution.

- Extension of network access beyond connected site – each ACT Network Site is permitted to extend access to end users beyond the site provided that the following items are true:

- Institutions in question must be a partner of an ACT CTSA hub currently participating in the network.
- The ACT CTSA hub is ultimately responsible for controlling end user access and abiding by ACT policies set forth in this document, including but not limited to the ACT Terms of Query Access.
- A local data agreement must be in place between the partner institution and the institution with connection to the ACT Network.
- If the partner institution has data that can be contributed to the ACT Network, then the partner institution may stand up its own ACT instance and connect directly to the network as an affiliate institution.

- Utilization Reporting – each ACT Network Site will provide reporting to the ACT Executive Committee on numbers of users and queries on a regular basis facilitated by the ACT Evaluation team, local Data Steward and national project manager.

- Feedback from users – each ACT Network Site will agree to survey their users for feedback as facilitated by the ACT Evaluation team and determined by the Executive Committee and ACT Evaluation team.

12. Terms of Query Access

The Terms of Query Access is designed to permit approved users access to the NCATS Accrual for Clinical Trials (ACT) Network SHRINE federated query tool for the purpose of requesting and receiving cohort counts from participating ACT Network Sites. Each Organization individually contributes and allows access to aggregate clinical data for research purposes only with an intention to accrue for clinical trials or for feasibility of clinical trials. This section provides a framework intended to ensure that research collaborations among the NCATS ACT Network investigators are realized in an ethical, respectful and transformative fashion.
Access to Data

- Access to data is limited to ACT Qualified Faculty, supervised Fellows or Qualified Staff working under a qualified faculty member. ACT Qualified Faculty, herein defined as faculty appointees at the participating ACT Network Sites who are

    - At or above Instructor level (Clinical and Research Fellows or doctoral students will be able to access cohort counts as approved by the Fellow's or student's designated faculty mentor) and

    - Either primarily appointed by, contractually related to, or on the medical staff of, or maintain a significant relationship with a participating ACT Network Site or partner institution.

- Faculty from outside of the ACT Network who wish to access data for research purposes must collaborate with a discipline appropriate Qualified Faculty member from one or more of the participating ACT Network Sites.

- Qualified Staff who wish to have access to the network must be approved by ACT Qualified Faculty.

- ACT Qualified Faculty are responsible for all queries conducted by their approved qualified staff.

- Sample sizes will be obfuscated +/- 10 and rounded to the nearest 5, and sizes smaller than 10 will not be returned in order to prevent inadvertent identification of the sampled patients. This is an inherent feature of the SHRINE software.

- All appropriate institutional, state and federal policies, laws and regulations governing specially protected information will apply and will be enforced by the site where necessary.

13. Standard Operating Procedures for ACT and ACT Sites

There are multiple Standard Operating Procedures (SOPs) developed for the ACT Network. Detailed information defining each SOP can be found in the ACT Standard Operating Procedures V6.0 document.

14. Conclusion

The contents of this document will continuously be reviewed and updated as appropriate to encompass the changes and growth of the ACT Network. Oversight and revisions are the responsibility of the ACT Governance Work Group with final sign off by the ACT Executive Committee.

APPENDIX A

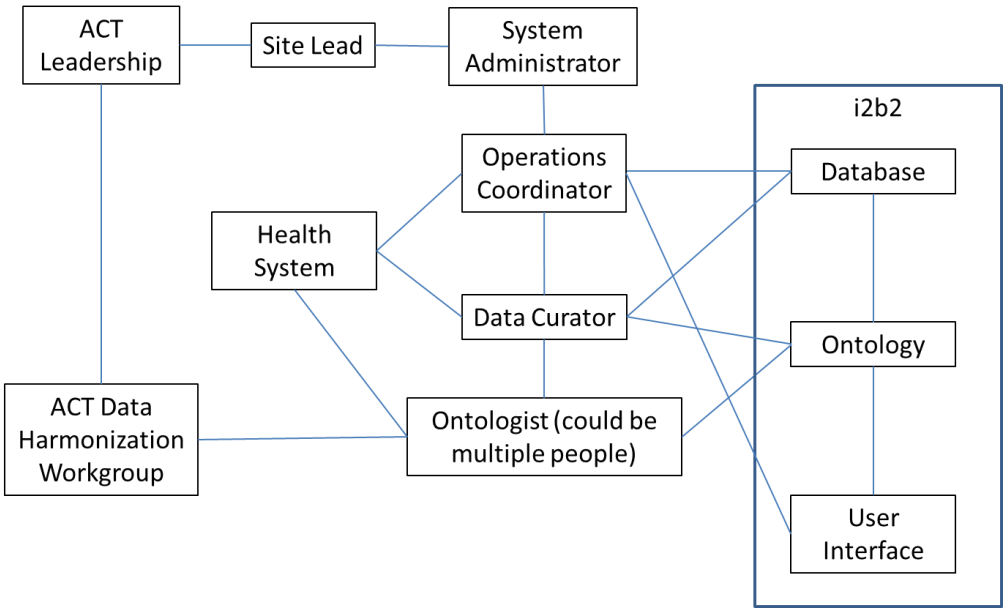
ACT Functions

Function	Responsibilities	Recommended Qualifications	Interaction Points	Duration of Role
Site Lead	Overall responsibility for site's activities in the ACT network.	Institutional approval to be PI of subcontract.	ACT Leadership. Oversees other roles.	Throughout project.
System Administrator (application and infrastructure)	**Application** -Installation, implementation, maintenance of SHRINE and i2b2 systems -Ability to provide deep level troubleshooting when needed -Communicate with project sponsors, leadership, other local technical resources, end users on an as needed basis **Infrastructure** -Well rounded knowledge of servers, operating systems -Familiarity with local (institutional) network operations, local IT policy, and experience with top-tier infrastructure and front-line service support	**Basic Qualifications** -BA / BS in Computer Science / Engineering or related field -Have at least 3+ years of system / network administration **Additional Qualifications** -Knowledge of Linux / Unix systems -Scripting (bash, python, etc.) -Database Administration (SQL, Postgres, Oracle, etc.) -Networking skills (firewalls, proxies, certificate / encryption methods, port configuration) -Web services (Apache Tomcat, Axis, WildFly, JDK)	-Works closely with SOC, other local technology contacts	-Focused effort in the early stages of joining the ACT Network to implement i2b2, SHRINE -Continued role in regular health and maintenance once on ACT production network
Site Operations Coordinator (SOC)	-Institution's main, day-to-day, point of contact for network operations, administration -Report status of routine network activities (software upgrades, data refresh activities) -Assist in compiling audit information for Data Steward -Assist in creating and deactivating users in accordance with local and network policy -Serve as point of contact for local end users	-Familiarity with project management concepts -Experience with Atlassian JIRA -Attention to detail -Good communication skills	-Works closely with System Administrator, Data Steward, Research Data Curator	-Necessary for duration of ACT network participation
Research Data Curator	-Ensuring accuracy and compliance of research data available to the ACT network -Perform data mappings as needed -Provide feedback on local data availability to assist in development of ACT ontology -Respond / troubleshoot data anomalies discovered on the network	-Prior experience with i2b2, SHRINE, ontologies, ETL and data mapping -Have at least 2+ years of database administration -Knowledge of scripting methods (SQL, Python, etc.) -Familiarity with local EHR and research data handling processes -Familiarity with scientific research topics highly valuable	-Works closely with SOC	-Necessary for duration of ACT network participation

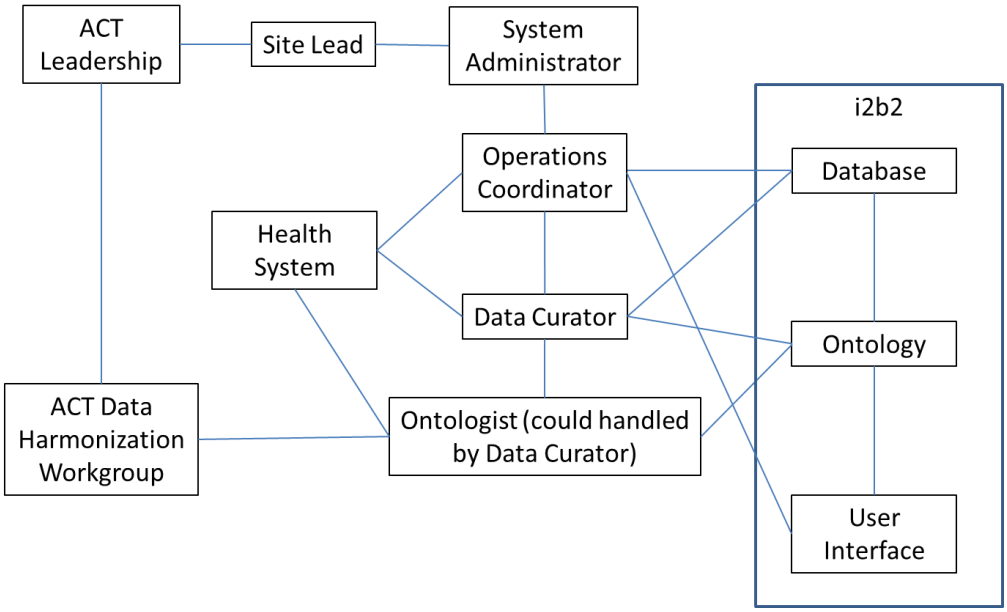
Data Steward (User Liaison)	-Serve as contact for users (researchers) with questions or problems using the network -Monitors research network behavior per the Terms of Query Access -Ensures appropriate use of the network -Serves as point of contact for other institution Data Stewards, as necessary	-Experience with biomedical research topics -Bachelor's or Master's degree in a related field is desired -Good communication skills -Attention to detail	-Works closely with the System Administrator and/or Site Operations Coordinator	-Onboarded prior to local dissemination of ACT to end users -Regular role throughout participation in ACT network
Dissemination Lead	-Conducts ACT related communication and outreach activities to local CTSA investigators	-Good communication skills -Ability to facilitate rollout of ACT to local end users	-ACT Dissemination & Evaluation Work Group	-Immediately following the technical implementation of ACT, if not before, and continue through participation in the network
Ontologist (if available)	-Mapping local terminologies to standards -Collaboration on ACT ontology development and participation in the ACT Data Harmonization Work Group	-Understanding of ontology principles -Patient care and/or health systems domain knowledge	-Research Data Coordinator -ACT Data Harmonization Workgroup	-Immediate and for duration of project -This is an optional role; mapping tasks could be carried initially as a team effort (with extra resources) and then handled by research data curator in maintenance mode

ACT Functions Interaction Points

Onboarding



Maintenance



System Use