Governing the ImproveCareNow Network

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version 1.2.2

Introduction

This report recommends governance changes for the ImproveCareNow (ICN) Network. They are designed to help the ICN Network adopt community-led stewardship, adapt its data governance to modern risks, and better realize the Network's values in practice.

The ICN Network has achieved unquestionable clinical success, thanks to its vibrant community of practitioners, researchers, patients, and families; and the ongoing support of Cincinnati Children's (CCHMC), the University of Vermont (UVM), and ICN Inc. As a result, the ICN Network is poised to reach the next stage of a learning network's evolution: self-governance.

This evolution comes at a critical time. As the ICN Network faces novel questions about data use and reuse, it is vitally important to keep the trust of its patient and practitioner community. The best way to do so is to integrate ICN's stakeholders into the Network's governance and decision-making.

There is much to be done. The Network is effectively operated by a single hospital, Cincinnati Children's (CCHMC). A separate nonprofit, ICN Inc., may have *de facto* responsibility for the network's governance, but that is not well-documented or formalized. The network's written procedures and policies for handling data are outdated, ad hoc, or nonexistent. Patients and families are involved in the Network on paper, but have little in the way of formal authority or guaranteed representation in key decisions.

This report explores how the ICN Network and its key partners can develop and implement community-driven governance over the Network and its data. It relies on a review of legal agreements, bylaws, and policies, and accompanying desk research, and various conversations with ICN Network stakeholders.

Part One of this report focuses on the collaborations that make the network run: between ICN Inc., Cincinnati Children's, and the Network writ large. Part Two focuses on the governance of the ICN Network's digital assets. Part Three includes an FAQ, a restatement of the report's recommendations, and enabling questions for the ICN Network. An Appendix contains additional worksheets to help plan implementation of the report's recommendations. Throughout, the report includes margin notes with additional commentary and resources .

Version 1.2 of this report was shaped by a March 2020 workshop with members of the Digital Asset Committee. The workshop agenda consisted of three primary activities: 1) ranking this report's recommendations in in order of perceived importance; 2) assembling a sample board composition; and 3) collecting questions for an FAQ.

The outputs of the workshop's activities have been integrated into the report's core recommendations. The committee's recommendation ranking can be found at the end of Parts One and Two.

Special thanks to the workshop's participants, who provided invaluable insight about the ICN Network:

- Catalina Berenblum, patient representative
- Chris Leff, attorney for ICN Inc
- Inbal Kavaler, parent representative
- Kate Harrow, ICN Project Manager
- Kelsey Thome, ICN Network Coordinator
- Lisa Pitch, parent representative

- Mary Havens, ICN Communications Specialist
- Michael Seid, CCHMC
- Peter Margolis, CCHMC
- Richard Colletti, UVM/ICN Inc.
- Shehzad Saeed, Dayton Children's Hospital
- Steven Steiner, Riley Hospital for Children/Indiana University
- Traci Jester, Children's of Alabama/UAB

Note: The relevant entities and initiatives have overlapping and confusing names. For clarity:

- *References to **ICN, Inc.** or **ICN Inc** refer to the Vermont nonprofit.*

- *References to the **Network** or the **ICN Network** refer to the initiative, rather than any specific entity. References to a network in lower-case are context specific.*

- *An **ICN Network Participant** or **member** refers to member care centers.*

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Glossary

BAA   Business associate agreement

CCHMC   Cincinnati Children's Hospital and Medical Center

CSA   Consulting Services Agreement. Here, CSA refers to the agreement between ICN Inc and CCHMC to operate the ICN Network.

ICN Inc   ImproveCareNow Inc, a Vermont-incorporated nonprofit.

ICN Network   The ImproveCareNow Network, a collaboration of children's hospitals, researchers, patients and families.

PAC   Patient Advisory Council

PDUA   Participant and Data Use Agreement. The agreement that member care centers sign to join the ICN Network.

PWG   Parent Working Group

Change log

Version 1.0
February 28, 2020

- Initial report draft

Version 1.1
March 9, 2020

- Added change log
- Added context to introduction and Part 1 about CCHMC's mission and learning networks
- Clarified ICN Inc's potential obligations as a BA
- Added HHS guidance on BA responsibilities
- Clarified definition of registry "chain of custody"
- Added HHS guidance on multi-party BAAs
- Moved note about data sharing policies into report body
- Correction about CCHMC employee's role in data request handling
- Minor spelling and typo correction
- Minor copy changes

Version 1.2
April 1, 2020

- Integrated outputs from March workshop into Section 1B's recommendations about the ICN Board
- Added sample board composition at end of Part 1
- Added outputs from March workshop that rank Part 1 and 2's recommendations by importance
- Added RAPID table for implementing recommendations
- Rewrote Part 3 to include FAQ.
- Moved worksheets to appendix A.
- **1.2.1**: corrected affiliations for workshop participants
- **1.2.2**: copy edit

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**ImproveCareNow Inc.,
Cincinnati Children's,
and the ICN Network**

The ICN Network's growth has outpaced its governance. Contracts no longer reflect the network's actual operations. There is limited or unclear documentation about the distribution of rights and responsibilities between ICN Inc, CCHMC, and the ICN Network community, especially related to data. To maintain its clinical success, the ICN Network needs a common, formalized vision for its long-term governance.

The ICN Network is organized as a multi-stakeholder collaboration around a shared set of resources: a patient registry database and a trove of co-created resources. The network's stakeholders include children's hospitals, clinicians, practitioners, researchers, patients, and families. To efficiently manage competing interests among stakeholders, collaborations such as the ICN Network often benefit from an independent steward. An independent steward is an entity purpose-built to manage a collaboration, and one that can be a vehicle for cooperative governance.[1]

Although ICN Inc is well-placed to act as the ICN Network's independent steward, it is not yet empowered to do so. The network's key legal and governing documents cement the ICN Network's dependence on Cincinnati Children's, at the expense of ICN Inc's formal authority. The network's key documents are ambiguous about the specific rights and responsibilities of each ICN Inc and Cincinnati Children's. ICN Inc itself lacks a formal commitment to representative governance.

This Part explores how ICN Inc could be empowered to serve as the ICN Network's independent steward.[2] It focuses on two discrete activities: clarifying the relationship between ICN Inc., Cincinnati Children's, and the ICN Network; and building and formalizing ICN Inc's governance capacity.

[1] Multiparty collaborations suffer from friction when the collaborations are built on many two-way agreements (which need to be separately negotiated) and when the collaborations are built on pooled assets (which raise freeloading problems). See A. Ogus (1986). *The Trust as Governance Structure*. The University of Toronto Law Journal, 36(2), 186-220. at 187-8 (describing challenges coordinating multiparty collaborations with contracts).

[2] These recommendations do not preclude long-term partnerships between ICN Inc and Cincinnati Children's (or other service providers). An ideal arrangement would give ICN Inc the best of both worlds: the nimbleness of a small organization backed with the resources of a large one.

The practice of building learning networks

Building learning networks is a key component of CCHMC's mission. How should learning networks grow to be self-governing, and what role should Cincinnati Children's (or another hospital) have in that growth over time?

The process of building and growing a learning network may be most analogous to a nonprofit incubating and spinning off a new organization.[3] A spin-off—and therefore a network—has three stages of growth:[4]

Stage 1: Incubation

- The parent hospital stewards the network. The network has no independent entity.

- The network's operations are entirely dependent on the parent hospital.

- The network has no independent governance.

Stage 2: Transition

- A independent entity stewards the network. The parent hospital has substantial influence in the entity's operations.

- Some of the network's operations are run independently, and some are contracted to the parent hospital.

- The parent hospital has substantial influence over the network's governance.

Stage 3: Maturity

- An independent entity stewards the network.
- The network's operations are run independently. If operations are contracted to the parent hospital, it is via a standard vendor contract.
- The network is self-governing. Parent has minimal or no board presence.

This may not be a fast process, and not every network will look the same in maturity. But regardless of their final form, networks should be designed from the outset towards a long-term governance structure.

Applied here, the ICN Network is somewhere in stage two.

[3] Typically, spin-offs happen because the child organization is pursuing a mission that is substantially independent from its parent. Here, the mission of a learning network is likely to still overlap with CCHMC's mission, which may justify a longer-term role in a learning network's governance.

[4] Adapted from Goldstein, et al., Vera Institute of Justice Spin-off Toolkit, 2007.

https://www.vera.org/downloads/ Publications/vera-institute-of-justice-spin-off-tool-kit/ legacy_downloads/ Vera_Tool_Kit_Final.pdf

The legal structure of the ICN Network

This section explores the legal agreements at the core of the ICN Network, and makes recommendations to untangle, clarify, and improve them.

In particular, this section highlights gaps between how the network actually operates and how the network's documentation suggests that it operates. Some of this variance is normal: people develop informal routines that may not be reflected in formally documented policies. Stretched too far, these ambiguities inhibit the Network's ability to adapt to a changing technology landscape, and threaten the Network's commitment to its community and its values.

For the network to continue to flourish beyond its founding generation of leadership, changes to its governance and legal structure are needed.

This section makes three primary recommendations: decide on a long-term contractual arrangement for the network; formally allocate rights and responsibilities among key network stakeholders; and grant ICN Inc more agency to use the Network's IP.

Recommendation 1

Clarify the contractual relationships between ICN Inc, Cincinnati Children's, and the ICN Network.

Three entities are involved in the ICN Network's management: ImproveCareNow Inc. ("ICN Inc"), a Vermont-registered nonprofit; Cincinnati Children's Hospital Medical Center ("Cincinnati Children's" or "CCHMC"); and The University of Vermont ("UVM").

On paper, Cincinnati Children's is effectively responsible for operating the ICN Network:

- CCHMC has direct custody of the patient registry. The PDUA/BAA omits ICN Inc from the registry chain of custody.
- CCHMC employees handle the bulk of the Network's operations, via a consulting services agreement (CSA) with ICN Inc. UVM provides additional time and support to ICN Inc, but there is no formal contractual relationship between the two entities. As of this writing, ICN Inc is in the process of hiring its first full-time employee.
- Via the CSA, Cincinnati Children's has effective long-term control over any intellectual property (IP) its employees produce.
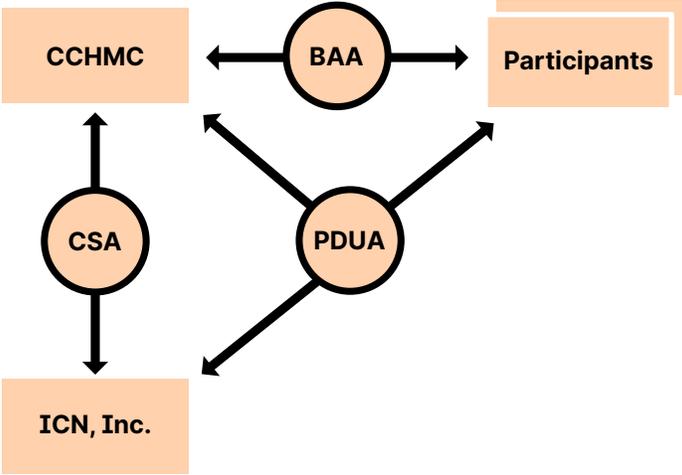
In practice, the picture is more complicated. ICN Inc appears to play a *de facto* role handling requests for data. The Participation and Data Use Agreement (PDUA) assigns some rights and responsibilities to "the Network", which is distinguished from the contract's other parties, but is itself not a legal entity.

Effectively, this means that some rights and responsibilities are assigned to no one.

ICN Inc's legal position relative to the network needs to be more clearly defined, and defects and ambiguities in the ICN Network's legal agreements need to be resolved.[5]

The registry chain of custody.

A major key to untangling the legal organization of the ICN Network is deciding whether ICN Inc should be included in the registry chain of custody: that is, whether ICN Inc should have direct responsibility over ICN registry data, even if the data is ultimately handled by another service provider. This decision will dictate the high-level architecture of the network.

Incorporating ICN Inc into the registry chain of custody: ICN Inc as network hub.

A simple reorganization of the ICN Network positions ICN Inc at the network's hub. To implement this, ICN Inc would execute BAAs and PDUAs directly with participating care centers. ICN Inc would then execute BAAs with service providers to manage the ICN registry and other resources.[6]
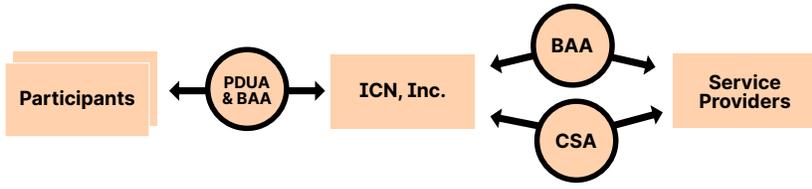
5 In general, this report assumes a continuing role for ICN Inc in the governance of the ICN Network. While CCHMC could theoretically subsume the functions of the ICN Network, it would be more difficult to build a governance structure that CCHMC did not effectively control.

The current contractual composition of the ICN Network. Because ICN Inc is not a party to the BAA, it is effectively excluded from the registry chain of custody. As a result, ICN Inc has little formal authority to make decisions about what happens to the registry data.

6 This could alternately be executed as a contract assignment. Here, CCHMC would assign its rights and responsibilities under the BAA and PDUA to ICN Inc.

This arrangement would create a clearer ownership and management structure for the ICN Network's data and resources. It would also create a clearer legal authority for ICN Inc to vet and authorize data requests, and to enforce ICN Network data and resource management policies. With this new authority comes new responsibility: ICN Inc would be subject to additional compliance requirements and liability as a business associate.[7]

The PDUA and BAA could also be combined into a single multiparty agreement, rather than as many bipartite or tripartite agreements.[8] This could signal to prospective participants that the network terms are trustworthy and not subject to negotiation.

Excluding ICN Inc from the registry chain of custody: the "binary star" structure.

For ICN Inc to assume a governance role in the Network, but still remain excluded from the registry chain of custody, its relationship with CCHMC (or a future service provider) would need to change.

7 *See* https://www.hhs.gov/hipaa/
for-professionals/privacy/
guidance/business-associates/
index.html
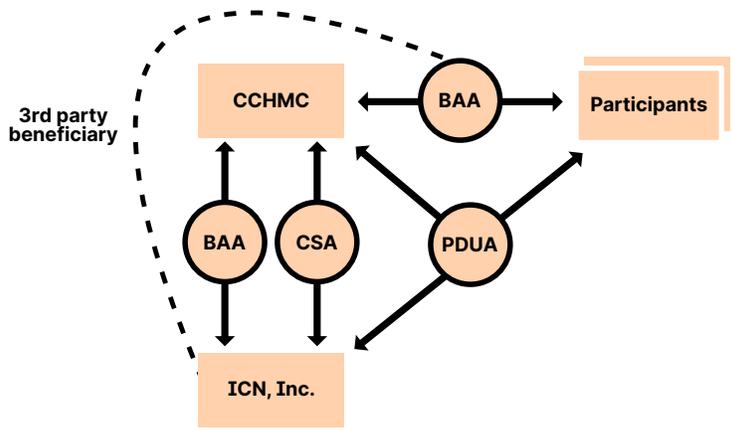
8 Similar to a Health Information Exchange (HIE), this agreement could be structured so that every member of the network is a BA of every other member, with ICN Inc providing a coordination and governance function. *See* "The HIPAA Privacy Rule and Electronic Health Information Exchange in a Networked Environment", U.S. Dept. Of Health and Human Services, https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/healthit/introduction.pdf

See also https://www.hhs.gov/hipaa/for-professionals/faq/540/who-is-liable-where-multiple-covered-entities-have-signed-a-single-business-associate-agreement/index.html

For stakeholders to govern the network via ICN Inc, it would need four additional rights. First, ICN Inc needs the right to vet and approve requests for registry data made by network members. Second, ICN Inc needs the right to limit the service provider's unilateral use of the registry data—as written, the BAA seems to allow CCHMC to circumvent a network-imposed data review process. Third, ICN Inc needs the right to monitor and enforce the use of registry data after a request has been fulfilled, along with enforcement rights over derivative resources created with ICN Network data. Finally, ICN Inc needs rights to designate a new service provider for the network.

While this would require fewer participant-facing changes than the network hub arrangement, the ultimate structure is more convoluted. It isn't clear that ICN Inc benefits from avoiding liability as a BA, especially if it would otherwise rely on its own BAAs with service providers to handle data processing.

Clarifying and amending the PDUA.

Regardless of the ultimate contractual arrangement, the Participant and Data Use Agreement (PDUA) needs to be clarified and improved.

Perhaps most critically, the PDUA has a pseudo-party, the "Network". Despite not corresponding to any party or entity, the Network is sometimes treated as a discrete contractual party, distinct from ICN Inc, CCHMC, and the Participant.

In the PDUA, the Network:
- Adopts policies and procedures for the participant to follow. (§2)
- Is the sole party able to publish, distribute, and make available reports at its own discretion. (§12)

How can learning networks grow?

As learning networks proliferate, hospitals might become members of multiple learning networks. The networks that Cincinnati Children's supports may have overlapping membership. Despite this, adding new members to a learning network continues to be slow and cumbersome, even if a prospective member already belongs to other learning networks.

A possible solution could take the form of a "network of networks" structure. Just as how a learning network serves as a trusted intermediary to other members' patient data, a "network of networks" could serve as a trusted intermediary to other learning networks, and a networked data exchange with hospital members.
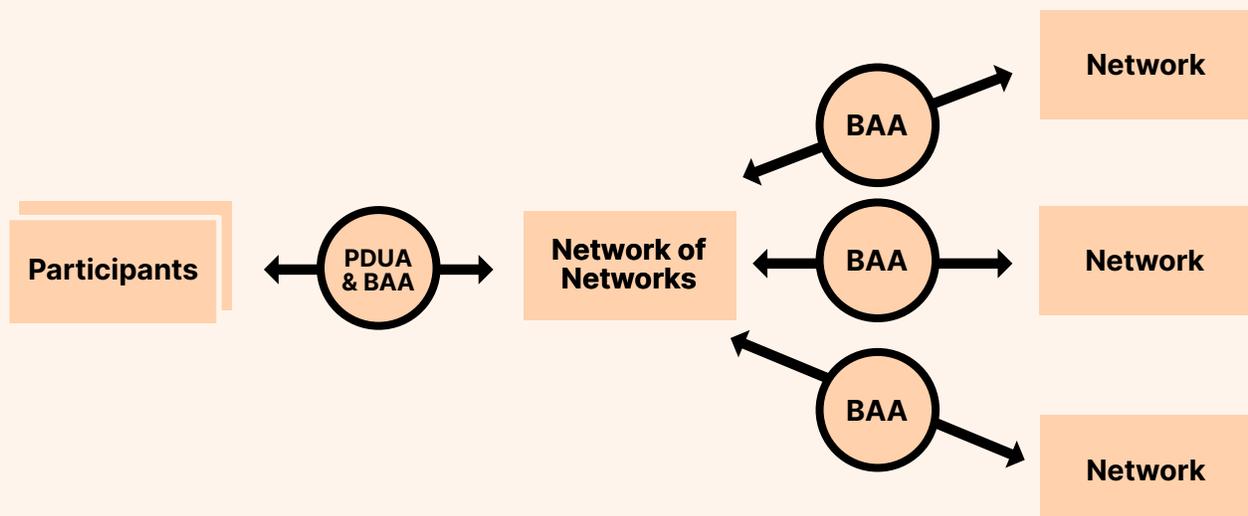
- Is required to notify Participant of any court order to disclose network reports. Assists Participant's effort to intervene in the court case as reasonably requested. (§13)

- Is required to conduct activities and protect confidentiality of data in accordance with HIPAA and other laws. (§14)

- Receives notification from the Participant if the Participant's contact person has changed. (§16)

These responsibilities should be moved to actual entities.

Other clarifications.

- **CCHMC appears to be excluded from the miscellaneous sections.** Among other things, this means that that ICN Inc and the Participant could modify the agreement without CCHMC's consent.

- **The PDUA should not be freely assignable.** Generally, best practice is to limit a contract's assignability, except when all parties consent.

- **Resolve contradiction about ICN Inc contacting community members.** ICN Inc is prohibited from contacting any patient in the database, which seems incompatible with ICN Inc's involvement with the ICN community.

- **Some sections are unclear about who they apply to, or what they require parties to do.** The PDUA doesn't make clear who owns the database (§11), what responsibilities the parties have to ensure responsible use of ICN registry data (§8), or who is responsible for implementing database safeguards (§6).

- **The BAA could be directly incorporated into the PDUA.** This would arguably simplify the onboarding process and reduce the possibility of conflicts between the PDUA and BAA.

- **Clarify the Participant's rights to access and request data from the Database, and its obligations upon doing so**. Currently, Participants lack clearly defined data access rights in the PDUA. This could be remedied via reference to an annex that includes the most current version of the ICN Network data access policies, along with a notation that the policies and procedures may change from time to time. This would ensure that care centers have already agreed to ICN's data sharing expectations prior to making a data request. An investigator could then reaffirm their commitment to the data sharing expectations upon making a data request. Including data access rights for participants in the PDUA could make the contract appear more appealing to prospective members.

- **Clarify the authority necessary to enforce data sharing policies.** A revised PDUA could more prominently incorporate these policies and apply them to participants. This would more effectively bind participating institutions to the Network's data policies. While there is already some authority to set and enforce a data sharing policy in the PDUA's §2, it does not assign ICN Inc (or any party) the right to actually set Network policies. In addition, the clause could require a stricter standard of compliance with the Network's data policies than the "reasonable effort" currently asked of Participants.

  Because data sharing policies may need to change over time, the PDUA can incorporate them by reference, and preserve the ability for ICN Inc to unilaterally modify them. In turn, this would likely require ICN Inc to notify participants of updated policies. Finally, ICN Inc would need to set internal processes for changing Network-wide data policies.

Selected division of responsibilities in the PDUA

ICN Inc

- Reports improper use or disclosure of data to Participant within 5 business days of ICN becoming aware. (§7)
- Agrees to make no attempt to identify or contact anyone to whom the PHI pertains unless such ID or contact is required by law (§9)
- Invoices participant for and receives Network fee. (§10)
- Can modify agreement with consent of Participant. (§24)

CCHMC

- Stores, manages, transmits, and analyzes data for Participant; generates reports. (§3)
- Agrees to use PHI only for purposes of improvement of quality of healthcare and patient health, also for research, and in BAA. (§5)

Unclear

- Safeguards shall be implemented and maintained to prevent use or disclosure of PHI in Database in non-permitted ways. (§6)
- All individuals and organizations given access to PHI in the database shall, as a condition of receiving access, agree to be bound by restrictions and conditions equal or greater to ones in this agreement. (§8)
- Who owns Database and derivatives (§11).

Participant

- Participates in the network and pays fee to ICN Inc. (§2, §10)
- Agrees to comply with Network policies and procedures. (§2)
- Submits data to CCHMC to store (§3). Warrants that it has the authority and consent to do so. (§3)
- Does not own the database or any outputs (§11)
- Will comply with HIPAA and Privacy Rule and will sign a BAA with CCHMC. (§4, §14)
- Agrees that reports from Network are confidential. (§12) Agrees to protect data and reports from discovery. (§13)
- Indemnifies ICN and CCHMC from claims by 3rd party based on disclosure of reports by Participant (§12) Won't hold ICN, CCHMC, or Network liable for actions of other participants (§18)
- Will notify Network about any change in contact person. (§16)

Network (pseudo-party)

- Adopts policies and procedures (§2)
- May publish, distribute, and make available reports at its own discretion. (§12)
- Shall notify Participant of motions to order disclosure of reports and shall assist Participant as reasonably requested in Participant's efforts to intervene. (§13)
- Shall protect confidentiality of data in compliance with HIPAA and other laws (§14)

Recommendation 2

Amend the Consulting Services Agreement to clarify rights and responsibilities between ICN Inc and Cincinnati Children's.

ICN Inc, Cincinnati Children's, and other key network stakeholders should formally allocate rights and responsibilities over the ICN Network. This exercise should be done twice: to identify where rights and responsibilities currently lie, and to identify where they should eventually lie. ICN Inc and CCHMC should more explicitly articulate responsibilities for the network in future CSA scopes of work.

The close relationship between ICN Inc and Cincinnati Children's muddles who in the network is ultimately responsible for making decisions. Ad hoc, under-documented routines have been implemented for some decisions. Other decisions documented owners. A lack of clear decision-making responsibilities and protocols make it harder for the ICN Network to adapt to novel scenarios, and for ICN Inc to assume more operational responsibility over the network.

To develop of a common understanding of who is responsible for tasks within the Network, ICN Inc and Cincinnati Children's can adopt a responsibility framework from the business world. This report uses RAPID, which is a variant of RACI developed by Bain.[9]

9 RAPID is a trademark of Bain. Other, related frameworks include RACI, MOCA, and RAM.

https://www.bain.com/insights/RAPID-tool-to-clarify-decision-accountability

The five elements of RAPID are:

- **Recommend** – Someone who brings forward a proposal or a request.
- **Input** – Someone who provides input to a proposal, but whose agreement may or may not be needed.
- **Agree** – Someone who must agree for the proposal to be carried out.
- **Decide** – The ONE person or body who decides and commits the network to a decision.
- **Perform** – Someone who executes the decision.

On the next page is a selection of network tasks that touch on data and ICN Network assets. Some tasks have multiple deciders—others have none. In many cases, it is unclear who has the right to provide input and agreement for a given decision.

Printable RAPID worksheets can be found in Appendix A.

Task	Recommend	Input	Agree	Decide	Perform
Admit new members.	New member			ICN Inc. AND CCHMC	ICN Inc Legal CCHMC Legal
Set terms of membership. (fee, rules, etc)		CCHMC		ICN Inc.	ICN Inc.
Host and manage patient registry data				CCHMC	Data Mgmt @ CCHMC
Handle requests for patient registry data.		Research committee reviewers		Research Director	Data Mgmt @ CCHMC
Set, monitor, and enforce data access terms.				Data Mgmt @ CCHMC	Data Mgmt @ CCHMC
Manage HIPAA compliance for registry data.				Data Mgmt @ CCHMC	Data Mgmt @ CCHMC
Handle cybersecurity and risk management for registry data.				Data Mgmt @ CCHMC	Data Mgmt @ CCHMC
Report improper use of registry data.				???	ICN Inc Legal CCHMC Legal
Store research derivatives.				CCHMC	CCHMC
Make research and resources available.				CCHMC	CCHMC
Change network data sharing policies.	???	???	???	???	???
Create community resources and assets.	Patients, Community	Comms Team	???	Peter M and Richard C	
Host and manage community resources and non-registry assets.				CCHMC	CCHMC
Permit access to the ICN Community.				???	???
Manage and monitor the ICN Community.				Comms Team	Comms Team
Handle compliance for the ICN Community.				Comms Team	Comms Team
Handle cybersecurity and risk management for the ICN Community.				Comms Team	Comms Team
Change ICN Community policies.				Comms Team	Comms Team
Collect new data from patients.			Patients?	???	???
Collect new data from members.				???	???

Recommendation 3

Grant ICN Inc more agency over the Network's intellectual property.

The current Consulting Services Agreement (CSA) effectively grants CCHMC ownership of all materials that CCHMC staff produces for the ICN Network. The CSA includes this section §9:

> *All written, printed, filmed, or taped material prepared by CHMC in the performance of this Agreement ("Material") shall be and will remain the property of CHMC. CHMC grants Customer a non-exclusive, nontransferable, royalty-free license to reproduce, disseminate, and display such Material(s) for its internal use. Customer shall not modify or amend any Materials or create any derivative works or improvements thereto (all such modifications, amendments, improvements o[r] derivative works collectively referred to as "Modification") without the prior written consent of CHMC. Modifications, whether authorized or unauthorized, will be solely owned by CHMC and shall be subject to the limited licenses and restrictions set forth in this Agreement with respect to Materials.*[10]

10 2010 CSA §9; 2007 CSA §10.

In other words, the CSA makes three claims:

First, that all materials that CCHMC staff produce for ICN Inc under this contract belong to CCHMC, not ICN Inc. At the time of this writing, ICN Inc has no staff, and the CSA appears to cover nearly all network activities. Hence, this would appear to cover

nearly all of the ICN Network's intellectual property.

Second, ICN Inc cannot make changes to any CCHMC-produced materials without CCHMC's express permission.

Third, even if ICN does make changes to any of CCHMC-produced materials, such as via another service provider, those updated materials would also belong to CCHMC.

While this does not appear to be the case in practice, a stringent reading of this agreement would effectively give CCHMC control over any material produced for the ICN Network, and any derivatives built from that material, even if those derivatives were produced by non-CCHMC employees. In addition, the limited license granted to ICN Inc. does not define "internal use". ICN Inc's activities could be construed as mostly "external"—that is, sharing materials with other entities or with the public.

The limited rights afforded to ICN Inc could handcuff it from enforcing policies and procedures related to ICN Network resources.

To be an effective steward of the ICN Network, ICN Inc should have more agency to use materials produced under the CSA. CCHMC staff have helped to create a wealth of resources for the ICN Network. For ICN Inc to continue stewarding those resources, it should retain a broader license to use, modify, and reuse materials produced under the CSA at minimum. CCHMC permission should not be required to build derivatives from or modify the materials. This change will require both a modification of current and future CSAs, and an agreement to change the licensing of past CSAs.

CCHMC could still retain a broad license to use materials produced under the CSA and their derivatives—they may be useful for other networks that CCHMC incubates, or they could be part of a network continuity plan for ICN. This can also ensure

that resources developed as part of this collaboration will continue to remain open and accessible.

In addition, the IP clause should accommodate pre-existing materials that CCHMC contributes to the ICN Network as part of the CSA. This is normally accomplished by a clause that distinguishes between materials produced for the agreement (Contracted Materials) and materials that a contractor produced before the agreement (Pre-Existing Materials). Here, ICN Inc would receive original rights to Contracted Materials and a license to use Pre-existing Materials.

Key takeaways

1. **Decide on a long-term plan for ICN Inc.** From an organizational management perspective, ICN Inc is in somewhat of a limbo: it is both an essential component of the ICN Network and formally omitted from the Network's data management.

2. **Formalize responsibilities for the ICN Network, both now and in the future.** It is not clear who has responsibility for data-related tasks within the network. Just as importantly, it is not clear who has the right to provide input into data-related decisions. These responsibilities need to be allocated and formalized for the Network to continue to grow.

3. **Open the Network's IP.** ICN Inc should have more agency to use IP developed under the Consulting Services Agreement, while preserving the ability of Cincinnati Children's to use materials to support other network-related activities. This will likely require an agreement to cover materials developed under past CSAs (which are signed annually), and changes to future CSAs.

The governance of ICN, Inc.

The ICN Network is a multi-stakeholder collaboration built around shared resources. While there is no single "best" governance model for these types of collaborations, empirical studies suggest four keys to success:[11]

1. **Inclusiveness.** The rules of a collaboration should not be made by a select few, but with the involvement (or potential involvement) of all actors who wish to participate.

2. **Clarity.** It is clear who is involved in the collaboration, and what their rights, responsibilities, and obligations are.

3. **Conflict Resolution.** There are effective systems for identifying and addressing conflicts quickly.

4. **Fairness.** Members perceive a fair relationship between what individuals invest in the management of the resource and the extent to which they benefit.

The recommendations in this section explore how ICN Inc can build formal bylaws and processes that are representative of the ICN Network's values, and that reflect these success factors.

[11] C Leviten-Reid and B Fairbairn, "Multi-stakeholder Governance in Cooperative Organizations: Toward a New Framework for Research?", *Canadian Journal of Nonprofit and social economy research*, 2(2):25-36, 2011, citing E Ostrom, "Reformulating the commons", *Swiss Political Science Review*, 6(1):29-52, 2000.

See also U Gasser, R Budish, and S West, "Multistakeholder as Governance Groups: Observations from Case Studies", Berkman Klein Center, 2015 (describing transparency, accountability, legitimacy, and effectiveness as common factors among successful governance arrangements);

See generally "10 Basic Responsibilities of Nonprofit boards", National Center for Nonprofit Boards, https://www.inphilanthropy.org/sites/default/files/resources/Ten%20Basic%20Responsibilities%20of%20Nonprofit%20Boards-Natl%20Center%20NP%20Boards.pdf;

See generally "Understand Your Responsibilities, Guidance for Board Members of Charitable Nonprofit Organizations in Vermont", Vermont Office of the Attorney General, 2015, https://ago.vermont.gov/wp-content/uploads/2018/01/Charitable-Nonprofit-Board-Guidance.pdf.

Recommendation 4

ICN Inc. should modify its bylaws to formally reserve seats for representatives of key network stakeholder groups.

A key challenge in building representative governance is: who ought to be represented? The makeup of a collaboration's board of directors is one signal about who the collaboration is ultimately for. The below matrix offers one analytical frame for determining whether to involve a stakeholder in an network's governance.[12]

12 N Vallejo and P Hauselmann, "Governance and Multi-stakeholder Processes", International Institute for Sustainable Development, 2004, citing Wye College, NGO Management, The University of London (1998).

Should a stakeholder be involved in a network's governance?

Network's ability to influence its stakeholders.

	Low	Medium	High
High	**Essential to involve**	**Essential to involve**	**Essential to involve**
Medium	**Desirable to involve**	**Desirable to involve**	**Essential to involve**
Low	**Involve if possible**	**Desirable to involve**	**Essential to involve**

Stakeholder's power to influence the network.

Matrix for determining whether a stakeholder should be involved in a network's (or other initiative's) governance.

The ICN Network's ability to influence patients and families justifies their involvement in the network's governance. While care centers have some ability to

express their disagreement with network policies by exiting the ICN Network, patients and families are unable to meaningfully escape the Network's influence. A patient (or their parent/guardian) may have signed a sweeping consent form and may perceive it as a condition of their long-term care. Even if a patient withdraws consent or isn't part of the ICN Network registry, or isn't aware of the Network at all, they are still likely to be affected by the research derived from ICN data—for better or worse.

ICN Inc should be representative of the network and community it stewards. While ICN Inc appears to have a relatively representative board, there is nothing in the current bylaws requiring such a composition. ICN Inc should amend its bylaws to formally reserve board seats for members of key stakeholder groups.

In a working dinner at the Fall 2019 Community Conference, members of the digital asset committee described the following network stakeholders:

Stakeholders

Patients[13]

Parents/Families/Guardians

CCHMC

Physicians/Clinical teams

Multidisciplinary professionals

Legal/Financial Institutional leadership

[13] Patients would likely need to be of majority age before being able to serve on the board.

At the March 2020 workshop, committee members discussed how these stakeholders might be represented on the board.

Patient-side representatives
Patients
Workshop participants noted the importance of having patient voices on the board, and the difficulty of sourcing patient directors. Adding to that is an age challenge: patients will need to be of majority age before they can serve, but typically "age out" of the ICN community at 25.

Participants suggested that patient representatives have staggered and slightly overlapped terms, so that there will always be a "junior" and "senior" representative. Committee members also suggested that a prospective patient board member could spend time as a non-director "observer", to understand how the board operates. Finally, the board could allow patient representatives to serve for a short time after they've aged out of the registry, to expand the potential pool of directors.

While there was some disagreement over whether this was feasible, the committee suggested that the board could have has many as two patient representatives with staggered, overlapping terms. In general, having multiple board representatives can help with institutional memory and continuity, better represent the diverse interests of a stakeholder group, and relieve some of the burden on individual directors.

Parents
Although there are ICN Inc board members who happen to be parents of children with Chron's diseases, committee members noted that this is not the same as having distinct parent representatives on the board.

The committee recommended two parent representatives for the board.

Support
Parents and patients will both need material support to participate on the board, including travel support, professional development resources, and accessible

meeting times. At minimum, ICN Inc should consider an honorarium for patient-side directors.

Care-side representatives
Physicians/clinical teams
The majority of workshop participants settled on two seats for physician representatives. (The full range of seat suggestions was 1-4)

Multidisciplinary professionals
Most workshop participants recommended a single seat for a multidisciplinary professional. Participants noted that sourcing a board representative here may be difficult.

Legal/Financial institutional leadership
Workshop participants generally recommended that institutional leadership have one or two board seats.

Support
Workshop participants suggested that care-side stakeholders would need orientation and some professional development, along with their home institution's consent to serve on the board.

Consolidation
As an alternative structure, one participant suggested that care-side representatives be consolidated into one category with four seats.

CCHMC and UVM
Given CCHMC's deep involvement in ICN Inc and the ICN Network, it would be appropriate for CCHMC to have a board seat to fill at its discretion. Most workshop participants agreed that CCHMC should have a board seat, but qualified that it should be contingent on CCHMC's continued role in (and support of) the ICN Network. Material earlier in this Part 1 offers guidance on how this board seat can be handled over time.

Similarly, as UVM is winding down its involvement with ICN, workshop participants recommended that UVM should not have a board seat.

Independent directors
Although they may not always be needed, ICN Inc's board could reserve the ability to appoint independent directors to meet specific skill needs for the board (e.g., finance), or to ensure that the board represents the demographic diversity of the network (e.g., race, gender, geography, size of care center).

Additional protections
ICN Inc could implement two additional protections to ensure representative decision-making. First, ICN Inc could change its quorum requirements, so that representatives of each stakeholder group must be present for a board meeting to commence, or for certain board actions to have effect. Second, ICN Inc could require the explicit approval of parent/patient board representatives for decisions that may adversely (or disproportionately) affect them.

The ultimate composition of ICN Inc's board is a decision for the network. Regardless, ICN Inc should invest professional development resources to help its directors understand their responsibilities and develop the necessary expertise to steward a learning network.

ENCOURAGE NEW LEADERS

Recommendation 5

ICN, Inc. board members should have terms and term limits.

ICN Inc could consider terms and term limits for some of its board members. While there is no static best practice for terms and term limits for board members, most nonprofit boards have terms and term limits for board members.[14] Common term limits are two three-year terms, or three two-year terms.[15] For the sake of organizational continuity, term limits are often staggered.[16] At the March workshop, participants mostly recommended that directors serve two three-year terms.

There is a deep, engaged community of potential board members within the ICN Network, and the process of regularly rotating and electing board members is likely to improve the community's engagement with the board. Terms and term limits prompt the board to practice onboarding and offboarding directors. Term limits may also be staggered within individual stakeholder groups to preserve institutional knowledge.

ICN Inc could allow term-limited board members to return after a cooling-off period, but this isn't recommended. ICN Inc's network of councils and committees provide ample opportunities for former directors to continue to engage with the network's governance.

The board chair could also be term-limited. Typically, a board chair is elected by the board of directors. The most common practice in nonprofit boards is to limit the chair to two consecutive one-year terms. Other offices that require specialized skills, like treasurer, may also have one-year terms, but with longer or no term limits.

14 BoardSource, "Leading with Intent", 2017 Index of Nonprofit Practices. https://leadingwithintent.org/wp-content/uploads/2017/11/LWI-2017.pdf

15 Id.

16 Id.

Recommendation 6

ICN, Inc. could adopt membership, and create community-driven systems for electing board members.

For board members to represent stakeholders, stakeholders must have a role in choosing board members. The method of choosing board members will likely differ depending on the stakeholder group.

For care center representatives, ICN Inc could adopt a limited form of membership.[17] Participating, dues-paying care centers could be limited voting members of ICN Inc, with the ability to elect physician or care center board members. One way to implement this is to have the bylaws grant the board of directors the right to nominate a slate of directors. The board would then have discretion to build a nominating process, which could be based on an open solicitation. From there, the membership would select the directors.[18]

Because of the small size of the active ICN community relative to the total patient population, it may be logistically difficult to create representative voting membership for parents and patients, at least in the short-term. To elect parent and patient board representatives, ICN Inc could lean on pre-existing working groups, councils, and committees. Workshop participants recommended that parent and patient directors be appointed through a combination of board nomination and PWG/PAC approval, or vice versa.

17 For examples of board bylaws with forms of membership, see

PCPI Foundation Bylaws, https://www.thepcpi.org/resource/resmgr/docs/2019_bylaws_approved_current.pdf

Online News Association Bylaws, https://journalists.org/wp-content/uploads/2018/08/ONA-Bylaws-July-2018.pdf

18 The board could continue to nominate and elect its own members, but this would put more responsibility on the board to mentor members and ensure succession planning.

LEVERAGE THE COMMUNITY

Recommendation 7

Formalize councils and working groups, and use them as a governance resource.

Not everyone can meaningfully or equally participate in a network's governance: flying to events may be an unaffordable expense; work or family obligations may make it difficult or impossible to call into a meeting; the time needed to invest in serving on the board of a nonprofit may be prohibitive.

Committees, councils, and working groups are a great way to tap the wealth of the network's expertise, without the full demands of a directorship. The ICN Network already features several informal advisory councils, working groups, and committees, with various degrees of formal responsibility. The ICN Inc bylaws could formalize these committees (and their makeup), give them responsibilities and a board presence, and nurture them as a governance resource.

As ICN Inc adds full-time staff, it will likely need to revisit its board committees. At minimum, ICN Inc likely need a governance committee to manage new administration and HR issues.[19]

Committees, councils, and working groups with formal responsibilities should be held to similar representation standards as the board. Participants in the March workshop noted that although parents and patients were nominally members of ICN committees and working groups, in many cases the actual operation of those groups does not meaningfully involve them. For example, committee meetings are often scheduled during workdays and schooldays, when patient-side representatives cannot participate.

19 Additional resources for internal controls and HR policies can be found in Part Three's FAQ.

Recommendation 8

Establish a more robust conflict of interest policy that accounts for non-financial conflicts of interest.

Although ICN Inc has a conflict of interest policy, it focuses only on financial conflicts of interest. As ICN Inc assumes a more direct stewardship role over the ICN Network, it should develop a policy that better addresses the full range of conflicts a multi-stakeholder network is likely to encounter.

In a for-profit corporation, conflicts of interest are often straightforward: a board member might have a personal financial interest that conflicts with a company's interest (such as owning a building the company is renting from); or a board member might represent a major investor in the company. In each case, the conflict is usually managed via disclosure and recusal: in the above cases, the conflicted board member would recuse herself from participating in discussions about rent renewal; or from the board's discussion of the investor's offer to buy a larger share of the company. For conflicts related to vendors, organizations often write procurement policies requiring a minimum number of independent bids, or require an open RFP process for contracts above a certain size.

Multi-stakeholder networks like ICN present subtle, complex conflicts that are less common in the corporate world. Board members are explicitly representing their stakeholder groups or institutions for the network.[20] In addition, board members may sometimes have to balance a duality of interests: where they may have a personal interest in an issue

20 Applied to ICN Inc, CCHMC's board representative would recuse herself from ICN Inc's board discussions about negotiating consulting agreements with CCHMC.

that may differ from the stakeholder group they represent. These interests may not always be financial.[21] For example, a clinician might have a personal interest in delaying tighter data access policies because it will benefit her own research; or a parent might have a personal interest in making it easier to for patients to join clinical trials. Cases like these underscore the importance of disclosing relationships that may influence a director's (or officer or committee member) decision-making. Not every relationship constitutes a disqualifying conflict, but it is ICN Inc's responsibility to consistently identify and manage potential conflicts.

A revised conflict of interest policy should be incorporated into the bylaws, and cover committee and council members in addition to the board and the organization's executives.

Managing conflicts between members

ICN Inc could consider building infrastructure for managing conflicts between network stakeholders, via a conflicts committee. It isn't clear how often such a committee might be used, but building infrastructure for efficiently managing and adjudicating conflicts is a key to successful multi-stakeholder governance initiatives.

[21] *See also* J.Masaoka, "Non-profit conflict of interest, a 3-dimensional view", Blue Avocado, 2010

https://blueavocado.org/leadership-and-management/nonprofit-conflict-of-interest-a-3-dimensional-view/

Secondary recommendations

Recommendation 9
ICN Inc should create committees with data-related responsibilities.

ICN Inc should create one or more committees to manage data-related issues. Committees could be responsible for maintaining data-related policies, from data sharing to risk management, and help to set terms and conditions on data requests. Because of the tension between openness and protecting privacy, ICN Inc should consider standing up multiple committees with narrowly-defined responsibilities, rather than an large data committee with nebulous responsibilities.

Recommendation 10
ICN Inc should create an equity committee.

Equity is an increasingly central concern for learning health systems.[22] ICN Inc should create an equity committee to both evaluate the Network's performance from an equity lens, and identify opportunities to reduce inequities in research and treatment.

22 *See, e.g.,* D Brooks et al., "Developing a framework for integrating health equity into the learning health system", Learning Health Systems 1(3) 2017 https://doi.org/10.1002/lrh2.10029

Recommendation 11
ICN Inc should create whistleblower and document retention policies.

Partially as a result of Sarbanes-Oxley, which prohibits retaliation against whistleblowers, it is considered best practice for organizations (nonprofits included) to have both whistleblower and document retention policies.

Recommendation 12
ICN Inc should create a network continuity plan.

As ICN Inc assumes a greater stewardship role in the ICN Network, the need to plan for disaster grows more acute. ICN Inc should develop and maintain a network continuity plan, designed to help the ICN Network continue in the event of catastrophic data loss at a service provider, or even in the event of ICN Inc's closure. At minimum, this may involve a secure backup of ICN Network assets stored with a trusted party.

Key takeaways

1. **ICN Inc should modify its bylaws to formally reserve seats for representatives of key network stakeholder groups.** The final selection of the stakeholder groups and their board representation is a decision for ICN Inc, CCHMC, and the ICN Network. Inclusiveness is a key element of successful multi-stakeholder governance, and the composition of ICN Inc's board is a public signal about who the network is ultimately for.

2. **ICN Inc board members should have terms and term limits.** ICN Inc should choose between three two-year terms or two three-year terms for most board members. Institutional board seats (such as CCHMC) and independent directors selected for professional skill (such as finance) may have more relaxed term limits. The board chair should also be term-limited: two one-year terms is most common.

3. **ICN Inc could consider membership and other community-driven methods for electing a representative board.** Participating care centers could earn limited membership in ICN Inc, which would entitle them to vote for some board seats. For stakeholder groups where the membership is so diffuse that voting may be impractical (such as parents and patients), ICN Inc can leverage existing advisory council and working groups to select stakeholder representatives to the board.

4. **Formalize councils and working groups and rely on them as a governance resource.** ICN Inc should incorporate standing committees, councils, and working groups into its bylaws, and formalize rules and responsibilities for each.

(5) **ICN Inc should update its conflict of interest policy to account for non-financial conflicts of interest.** Currently, ICN Inc's conflict of interest policy covers financial conflicts of interest. Nonprofits with representative boards often encounter non-financial conflicts of interest or dualities of interest. A robust conflict of interest policy should include disclosure and recusal processes for managing those potential conflicts.

(6) **Secondary recommendations.** ICN Inc should create data and equity committees, whistleblower and document retention policies, and a network continuity plan.

Building the ICN Inc board of directors

The following is a sample board composition for ICN Inc, based in part on feedback from participants in the March workshop. It presents a largely representative board, with the potential for additional appointments to fill skill or diversity needs.

Stakeholders	Board Seats	Term	Term limit	Method of selection
Patients	2	3 years	2 terms	Board + PAC
Parents/Families/Guardians	2	3 years	2 terms	Board + PWG
CCHMC[a]	1	3 years	2 terms	CCHMC appointed
Physicians/Clinical teams	2	3 years	2 terms	Member election
Multidisciplinary professionals	1	3 years	2 terms	Member election
Legal/Financial Institutional leadership	1-2	3 years	2 terms	Member election
Independent directors	0-3	3 years	2 terms	Board appointed

Board-level committees[b]	Skills needed	Diversity measures
Finance	Finance	Gender
Governance (Admin/HR)	HR/Operations	Race/Ethnicity
Ethics	Ethics	Age
Data	Data + Technology	Size of care center
Equity		
Conflicts		
Audit		

[a] contingent on CCHMC's continued involvement with ICN

[b] Note: Board-level committees may include non-directors

Workshop rankings, by importance

Recommendation	Average rank	Catalina Berenblum	Chris Leff	Inbal Kavaler	Kate Harrow	Kelsey Thome	Lisa Pitch	Mary Havens	Michael Seid	Peter Margolis	Richard Coletti	Shehzad Saeed	Steve Steiner	Traci Jester
Clarify the contractual relationships between ICN Inc., Cincinnati Children's, and the ICN Network. (R1)	2.46	6	2	1	1	1	2	5	4	6	1	1	1	1
Amend the Consulting Services Agreement to clarify rights and responsibilities between ICN Inc and Cincinnati Children's. (R2)	4.08	4	4	2	5	2	3	7	5	7	2	2	2	8
ICN Inc. should modify its bylaws to formally reserve seats for representatives of key network stakeholder groups. (R4)	4.84	8	10	3	2	8	7	3	1	1	5	3	7	5
Grant ICN Inc. more agency over the ICN Network's IP. (R3)	5.31	3	3	5	12	5	4	8	6	3	3	4	3	10
ICN Inc. should formalize its councils and working groups, and use them as a governance resource. (R7)	6.00	2	8	8	11	4	6	2	7	5	11	6	5	3
ICN Inc. should create a network continuity plan. (R12)	6.23	1	1	7	10	6	1	9	11	10	8	11	4	2
ICN Inc. could adopt membership and create community-driven systems for electing board members. (R6)	6.31	7	11	6	4	10	12	1	2	2	12	5	6	4
ICN Inc. should establish a more robust conflict of interest policy that accounts for non-financial conflicts of interest. (R8)	7.31	12	5	9	6	9	5	12	3	4	4	9	11	6
ICN Inc. should create committees with data-related responsibilities. (R9)	7.85	5	7	10	7	3	8	6	12	9	9	8	9	9
ICN Inc. board members should have terms and term limits. (R5)	8.38	9	12	4	3	11	11	10	10	8	6	10	8	7
ICN Inc. should create an equity committee. (R10)	9.31	10	9	11	8	7	9	4	9	11	10	12	10	11
ICN Inc. should create whistleblower and document retention policies. (R11)	9.92	11	6	12	9	12	10	11	8	12	7	7	12	12

Recommendation	Recommend Someone who brings forward a proposal or a request.	Input Someone who provides input to a proposal, but whose agreement may or may not be needed.	Agree Someone who must agree for the proposal to be carried out.	Decide The ONE person or body who decides and commits the network to a decision.	Perform Someone who executes the decision.
Clarify the contractual relationships between ICN Inc., Cincinnati Children's, and the ICN Network. (R1)	CCHMC or ICN Inc	Network membership	Cincinnati Children's	ICN Inc.	ICN Inc Legal CCHMC Legal
Amend the Consulting Services Agreement to clarify rights and responsibilities between ICN Inc and Cincinnati Children's. (R2)	CCHMC or ICN Inc	Network membership	Cincinnati Children's	ICN Inc.	ICN Inc Legal CCHMC Legal
Grant ICN Inc. more agency over the ICN Network's IP. (R3)	CCHMC or ICN Inc	Network membership	ICN Inc.	Cincinnati Children's	ICN Inc Legal CCHMC Legal
ICN Inc. should modify its bylaws to formally reserve seats for representatives of key network stakeholder groups. (R4)		Network membership		ICN Inc BoD	ICN Inc Legal
ICN Inc. board members should have terms and term limits. (R5)		Network membership		ICN Inc BoD	ICN Inc Legal
ICN Inc. could adopt membership and create community-driven systems for electing board members. (R6)		Network membership		ICN Inc BoD	ICN Inc Legal
ICN Inc. should formalize its councils and working groups, and use them as a governance resource.(R7)		Network membership		ICN Inc BoD	ICN Inc Legal
ICN Inc. should establish a more robust conflict of interest policy that accounts for non-financial conflicts of interest. (R8)				ICN Inc BoD	ICN Inc Legal
ICN Inc. should create committees with data-related responsibilities. (R9)		Network membership		ICN Inc BoD	ICN Inc Legal
ICN Inc. should create an equity committee. (R10)		Network membership		ICN Inc BoD	ICN Inc Legal
ICN Inc. should create whistleblower and document retention policies. (R11)				ICN Inc BoD	ICN Inc Legal
ICN Inc. should create a network continuity plan. (R12)		Network membership		ICN Inc BoD	ICN Inc Legal

2

Governing the ICN Network's digital assets

Datafication and machine learning offer a wealth of new health research opportunities. They also pose novel risks that can harm patients and undermine the trust relationships that bind a learning network together.[23] IRBs that cover human research have been slow to adopt to big data-related risks.[24] Data science and machine learning have yielded new ways to discriminate against and harm individuals, even on existing or public data sets, and existing ethical standards have yet to fully catch up. The future of health data initiatives will hinge on striking the right balance between advancing medical knowledge and minimizing data-related harm to patients.

This Part explores how the ICN Network might strike that balance. It makes a mix of legal, technical, and governance recommendations to help the ICN Network modernize its data request process, and to help the Network realize its values through formal policies. This Part also covers the ICN Network's community, and makes high-level recommendations for its management and redesign.

Note: This Part 2 refers to the ICN Network as the primary actor for implementing these recommendations. In Part 1, the question is left open about who will represent the ICN Network. Whoever answers that question ultimately bears responsibility for implementing the recommendations in this Part 2.

[23] *See also* C Petersen The Future of Patient Engagement in the Governance of Shared Data. eGEMs (Generating Evidence & Methods to improve patient outcomes). 2016;4(2):6. doi: 10.13063/2327-9214.1214

[24] *See also* N Raymond, "Safeguards for human studies can't cope with big data" Nature 568, 277 (2019) doi: 10.1038/d41586-019-01164-z

M Prosperi, J Bian. "Is it time to rethink institutional review boards for the era of big data?". Nat Mach Intell 1, 260 (2019). doi: 10.1038/s42256-019-0059-7

Patient data

This section describes the governance of the ICN Network's registry data. It focuses on classifying and interrogating requests for registry data. In addition, this section explores how the ICN Network can use the registry to formalize commitments to the network's values.

Classifying decisions

As data requests to the ICN Network grow in volume and variety, it is critical to have well-defined processes for handling these requests. From an organizational management perspective, a simple way to classify potential decisions is by their **frequency** and **impact**.[25] Each decision type is handled differently:

- **Low-impact, frequent decisions** are delegated to specialized teams. Here, the ICN Network might frequently provision access to secure data environments to network PIs with IRB approval. While it is important that the network be aware of these requests, cross-cutting network teams may not need to be involved in approving them

- **High-impact, frequent decisions** require cross-cutting involvement across the network. Here, the ICN Network will face frequent requests to egress data and research outputs from secure data environments. This is the moment for the ICN Network to gather stakeholder approval and input, and to gain a commitment from the researcher to

25 *See* "Untangling your organization's decision-making", McKinsey & Co., https://www.mckinsey.com/business-functions/organization/our-insights/untangling-your-organizations-decision-making

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adhere to the network's data sharing, data protection, and equity norms. Decision-making processes should be well-defined, and well-tested.

- **High-impact, infrequent decisions** may be major bets that require the consent of the board, or the network writ large. For example, a non-network member might make a request for ICN patient data. Approving this request will require additional input from stakeholders, and may be required to pass a higher threshold of consent. Here, well-documented processes are essential, to ensure that network stakeholders have appropriate input at the right time.

Who needs to be involved in a decision?

High	Network stakeholders	Cross-cutting teams
Low	Executive team	Specialized teams
	Low	**High**

Impact (vertical axis label)

Frequency (horizontal axis label)

HIGH FREQUENCY, LOW IMPACT
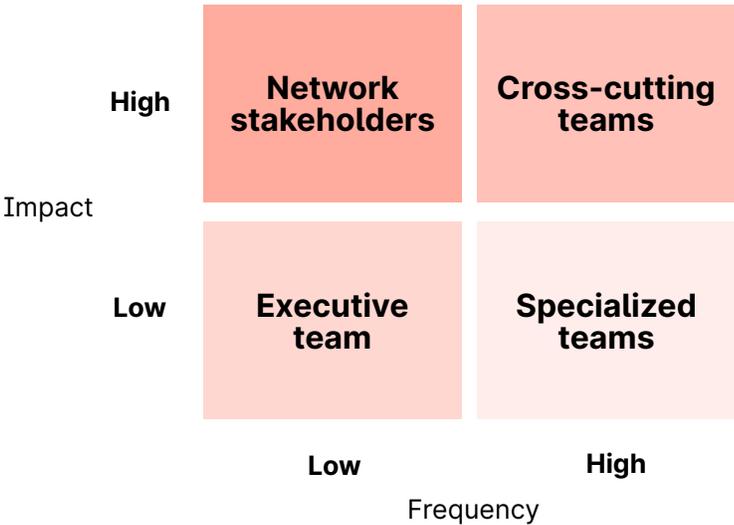
Recommendation 13

Create a preapproved process for network members to access and analyze data, while keeping it in network custody.

Learning networks are meant to encourage collaboration and research on a pooled dataset. To facilitate easier, safer access by network members, the ICN Network could adopt secure data environments.

Secure data environments are generally virtual machines preloaded with statistical software and a dataset. A user can remotely access a personalized instance of the virtual machine via a secure connection and use the statistical software to analyze the dataset. The user is unable to install new software on the secure data environment, or to extract any data from the environment without permission from the environment's host. Secure data environments are good fits for distributed networks of trusted parties, and are commonly used to facilitate safe networked access and analysis of sensitive data:

- **Johns Hopkins** uses secure data environments to allow intra-institutional researchers access to clinical data. This allows JHU to preapprove data requests from internal researchers with IRB approval. Once data leaves the secure environment, it faces an additional review.[26]

- **Vivli** is a clinical research hosting platform that uses secure data environments to allow access to clinical data and research.[27]

- **PEDSNet** uses a secure data environment to allow network members to work with their patient dataset.[28]

26 *See* "Johns Hopkins Launches New Precision Medicine Tools", https://www.hopkinsmedicine.org/news/articles/johns-hopkins-launches-new-precision-medicine-tools

See also "Research using the Precision Medicine Analytics Platform" https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/research_using_pmap.html;

"Data Trust" https://guides.library.jhu.edu/protecting_identifiers/datatrust

27 *See* "How to access data from Vivli and use the secure research environment", Vivli, https://vivli.org/vivliwp/wp-content/uploads/2019/03/2019_01_29-vivli-data-access-secure-research-environment.pdf

28 PEDSNet Policies, §6.10.1 https://pedsnet.org/documents/276/PEDSnet-Policies-v4-Board-Review_2019_03_19.pdf

Here, the ICN Network could use secure data environments to allow network members to access and analyze registry data. An in-network researcher with IRB approval could apply for access to a secure data environment, which could be limited in scope to cover their research request.[29] This request could be granted with an expedited review process, delegated to a functional team. Once the analysis is complete, the researcher can apply to export research products or other derivatives, which would then be subject to a full review process. The environment can then be spun down or retained to provide secure access to supporting data.

It is no longer necessary to send actual copies of datasets to requesting researchers, nor is it best practice to do so. Currently, ICN Network data is shared with researchers via files (CSV, Excel, or SAS) transferred through OneDrive. While OneDrive is a secure tool for file transfer, it is not ideal for controlling subsequent use of a dataset once downloaded. Most likely, a researcher will download a data file to their own machine, immediately violating the data sharing expectations document as written:

> *"Researchers must take appropriate steps to maintain data security (i.e., data cannot be downloaded onto laptop, desktop, or flash drive, etc., but must be maintained on password protected server)."*[30]

While the specific implementation recommended in this expectation is outdated, the sentiment holds: distributing copies of datasets as files is a data protection risk, because the files are increasingly difficult to account for.

Modern networking and virtualization technology means that the ICN Network no longer needs to take this risk. Combined with clearer legal agreements governing data sharing and use, implementing this recommendation could position the ICN Network as a trusted environment for sharing data among members.

[29] Some commercial vendors, such as Immuta, may provide products that offer a similar level of access control via a proprietary platform.

[30] ICN Network data sharing expectations document.

https:// d3n8a8pro7vhmx.cloudfront.net/ improvecarenow/pages/289/ attachments/original/1456428871/ ImproveCareNow_Data_SharingEx pectation_Policy_8-22-11_FINAL1.p df?1456428871

HIGH FREQUENCY, HIGH IMPACT

Recommendation 14

Adopt a risk-based approach for vetting data requests.

ICN Network should adopt a risk-based approach for vetting data egress requests and evaluating outside partnerships. This approach can also be used to decide whether ICN should collect and store data from other sources, and deciding on access policies for that data.

Currently, the ICN Network's data review process emphasizes the qualifications of the requesting researcher and the relevance of the research request to the ICN Network's dataset. Although the data sharing expectations document requests that the researcher not use the data "in a manner that creates harm to any individuals (such as exposing them to insurance or employment discrimination)", the review process does not evaluate whether a data request might increase the risk of harm.

Risk-based approaches are a better fit for a threat landscape transformed by datafication and machine learning. The explosion of health-related data and ways to analyze them creates new risks for patients. Together, more data and better data analysis tools make it easier to **identify** a specific person from de-identified data, to **classify** them as a member of a group (such as someone with Crohn's disease), and to **discriminate** against a person based on inferred attributes.[31]

Risk-based approaches are increasingly common tools to manage data-driven uncertainty, particularly

31 See also B Schneier "We're Banning Facial Recognition. We're Missing the Point.", New York Times, Jan 20, 2020. https://www.nytimes.com/2020/01/20/opinion/facial-recognition-ban-privacy.html;

Federal Trade Commission, Big Data: A Tool for Inclusion of Exclusion, January 2016, 7-11 https://www.ftc.gov/system/files/documents/reports/big-data-tool-inclusion-or-exclusion-understanding-issues/160106big-data-rpt.pdf;

K El Emam, "A Systematic Review of Re-Identification Attacks on Health Data", PLoS One. 2011; 6(12): e28071;

L Sweeney, Matching Known Patients to Health Records in Washington State Data. Harvard University. Data Privacy Lab. White Paper 1089-1. June 2013;

L Na, C Yang, C Lo, et al, "Feasibility of Reidentifying Individuals in Large National Physical Activity Data Sets From Which Protected Health Information Has Been Removed With Use of Machine Learning", JAMA Netw Open. 2018;1(8):e186040. doi:10.1001/jamanetworkopen.2018.6040

with the advent of GDPR. European data protection authorities now require Data Protection Impact Assessments to be carried out for high-risk data processing activities.[32]

Here, a risk-based approach would require the ICN Network to identify and minimize the risks that a given data request or partnership poses, and weigh whether an activity's potential benefit outweighs the potential harm to patients. These assessments should be done before data leaves the network's custody. Once out of network custody, it becomes much more difficult to manage how data is used.

Evaluating and mitigating risks: a sample framework

Risks can arise from a data request, the requester, or from proposed uses of data.[33] On the next page is a sample framework for identifying and evaluating data-related risks. Risk frameworks are living documents: they may need to evolve as technology changes or the ICN Network expands its activities.

[32] *See* "Guidelines on data protection impact assessment", European Commission, https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=611236;

See also "Framework for Data Sharing in Practice", Protection Information Management, Danish Refugee Council, http://pim.guide/wp-content/uploads/2018/05/Framework-for-Data-Sharing-in-Practice.pdf

See also "How do we do a DPIA?", Information Commissioner's Office (UK) https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/data-protection-impact-assessments-dpias/how-do-we-do-a-dpia/#how9

[33] *See* "Data Protection by Process", Future of Privacy Forum, 2019. https://fpf.org/wp-content/uploads/2019/12/WhitePaper_DataProtectionByProcess.pdf

Risk	Request	Requester	Use
Overly broad request. Is the request narrowly tailored to the scope of the research question? Can superfluous data or fields be eliminated from the request?	✓		
Disclosure-related harm. Does the content of the data itself pose a risk? Does the data make it easier to reidentify, classify, or discriminate against patients? Could this data be combined with other datasets, including public datasets or previous requests from ICN requests, in a way that could harm patients?	✓		
Inaccuracies. Is the data accurate? Are there deficiencies in the dataset that might yield a misleading result?	✓		
Mishandling. Where and how will the requested data be stored? Will it be subject to comparable security, integrity, and access controls?	✓	✓	✓
Intended uses of data or research. Are the research outputs likely to expose patients to harm? Could this research (or other network activity) be used by employers, insurance companies, or others to identify a person as having Crohn's disease or IBD, or to discriminate against them?	✓	✓	✓
Alternate uses of data or research. Could the research outputs be repurposed, reanalyzed, or recombined in a way that exposes patients to harm, including reidentification, classification, or discrimination?	✓	✓	✓
Bias and inequity. Could the research outputs produce guidance that favors or disfavors a demographic, racial, or socioeconomic group?	✓		✓
Conflicting purpose. Is the request from a for-profit company, an organization with a conflicting mission, or from an organization with duties to someone other than patients? Could the results of this research be sold to ICN patients or ICN Network members?		✓	✓

Mitigating risks

The ICN Network could deploy a variety of technical, legal, and procedural tools to mitigate data-related risks. These can be calibrated to the request, and could include:

Data minimization. A simple, effective mitigation is to narrowly tailor the request for data. At the request fulfillment stage, this could involve limiting the fields or records included in a returned dataset. Data minimization can also involve minimizing the time that a requester has access to a dataset.

Accuracy and integrity checks. Accuracy is a key component of emerging data protection standards. This mitigation should not only done at the time of a request, but should be a routine process for the network and its members.

Secure data environments. High-risk requests can be confined to the secure data environment managed by the network. An secure data environment could also be used to store and allow access to supporting data for published research.

Security audits and standards compliance. Rather than prescribing specific security measures for recipients of network data, ICN could require compliance with industry or national cybersecurity standards. The National Institute on Standards and Technology (NIST) maintains standards and frameworks on data storage, privacy, and information security.[34]

Licensing and trusts. The ICN Network could use legal agreements to guarantee the network's continued access to products derived from its data, and possibly to stymie unwanted derivatives and uses. ICN's data sharing agreements should, at minimum, guarantee the ICN Network a license to access, use, relicense, and repurpose research and products derived from its data.[35] These rights can then be extended to current ICN Network members.

34   National Institute of Standards and Technology, Cybersecurity Framework, https://www.nist.gov/cyberframework;

See also Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, "Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients", https://www.phe.gov/Preparedness/planning/405d/Pages/hic-practices.aspx;

See also Yael Grauer, "Why is the healthcare industry so bad at cybersecurity?", Ars Technica, February 9 2020, https://arstechnica.com/information-technology/2020/02/why-is-the-healthcare-industry-still-so-bad-at-cybersecurity/

35   Just as in some software licenses, the data license could be "infectious", meaning that any derivatives produced from the data are also subject to the terms of the original data license. The license itself could also give ICN Inc. (or whoever runs the network) the ability to enforce the license terms on the network's behalf.

The ICN Network could consider trusts as a legal tool to prevent unwanted uses of Network data.[36] A trust is a legal device to own something for the benefit of another. Here, a licensee of data would instead be a trustee, and would be obligated to use the data exclusively in the best interests of the Network. ICN Inc (or ICN Inc and the ICN Network's members) could be beneficiaries of the trust, and would ultimately own the data and all of its derivatives.[37] If a trustee violates the terms of a trust, it may be easier to reclaim the software or data derivatives she has improperly built than it would be with a license.[38]

Capacity-building and stress-testing. Building robust data governance is ultimately as much about capacity as it is about good process. The ICN Network should invest resources in training stakeholders to understand, evaluate, and mitigate data-based risks. This should include professional development for committee and board members.

As part of this, the network should ensure that its members and stakeholders are well-practiced in identifying and mitigating risks. Requesters should be prompted to assess and mitigate risks of their own research as part of their data request. Controversial or high-risk data request scenarios could be gamed out in advance, to help the network work out how to manage them.

[36] Here, trusts should not be confused with the term "data trust", which is often used to refer to generic data management arrangements, rather than the legal form of a trust. For example, the Hopkins "Data Trust" referenced above does not appear to be an actual trust.

See also K Porcaro, *In Trust, Data: The Trust as a Data Management Tool* (March 29, 2019). https://ssrn.com/abstract=3372372

[37] *See* A. Edwards, et al. *A trust approach for sharing research reagents*. 9 Science Translational Medicine 392 (31 May 2017). DOI: 10.1126/scitranslmed.aai9055;

See also SGC Open Science Trust Agreement, Structural Genetics Consortium (https://www.thesgc.org/click-trust/).

[38] By default, trusts make available certain types of *equitable* remedies, which can allow for recovery of property that is derived from trust property. Contracts violations are typically addressed with *legal* remedies, such as monetary damages.

HIGH IMPACT, LOW FREQUENCY

Recommendation 15

The ICN Network should increase its stakeholder approval thresholds for higher-risk requests.

Technological advances will likely lead to more requests for ICN Network data from outside the network, including from non-health actors. The network policies are mostly silent on how external requests for data should be handled, other than requiring external researchers to collaborate with an ICN-affiliated researcher. Network policies are also silent about how to treat a request from an ICN-affiliated researcher on behalf of a corporate partner.

Although network policies allow for a relatively broad interpretation of what constitutes a permitted use of data, allowing outside parties to access the network's data could face resistance from network members and patients.

High-risk data requests require elevated patient engagement and risk mitigation. In addition, they should be subject to stricter approval requirements, with progressively deeper and broader involvement of network stakeholders. While high-risk requests will likely be rare, it is critical that the network have documented processes for handling them.

Stakeholder approval thresholds should be determined in advance. These could mirror the processes for filling board seats. For example, while the full parent working group may not be involved in approving a data request from an in-network researcher, the group's sign-off may be needed to approve a data partnership from an out-of-network

company. That partnership may also require consent from a supermajority of the network's voting membership.

At minimum, the decision to make data available to a non-network member is likely subject to board approval, because of its potential impact on the network.

This recommendation is not a substitute for stakeholder involvement in regular data requests: stakeholders should be well-represented on the committees and working groups that make regular data decisions. Nor should this be considered a recommendation to merely put every controversial data request to a simple vote: in some multi-stakeholder governance initiatives, a vote is a matter of last resort, for when consensus is out of reach.

Rather, **higher risk data requests should require more comprehensive stakeholder consent.**

Recommendation 16

Formalize data sharing expectations into data sharing policies.

The data sharing expectations document should be broken up into formal data sharing policies that bind ICN Network member institutions, and that are enforced by ICN Inc.

The data sharing expectations form is probably insufficient to meet the requirement in §8 of the PDUA, which states:

> "All individuals and organizations that are given access to PHI in the Database shall, as a condition of receiving such access, **agree to be bound by restrictions and conditions that are equal to or greater than those that apply to use and disclosure of PHI under this Agreement**." [39] (emphasis added)

The data sharing expectations form is written to bind individual researchers rather than their home institutions. Although this form may legally enforceable, researchers may interpret the conditions as suggestions rather than requirements. Finally, it isn't clear who the researcher is contracting with— and therefore who could enforce the contract.

To fix this, data sharing expectations should be elevated to Network-level data sharing policies, so they can be better turned into responsible data sharing practices that the whole network is committed to.

[39] Although this section is silent about which party it applies to, the most likely interpretation is that it requires CCHMC (who operates the database) to impose restrictions and conditions on individuals and organizations accessing the Database.

Substantively, the data sharing expectations document combines parts of four distinct policies that may be better separated and integrated into different parts of the Network's review and governance process.

- **Open Access**, which describes how accessible ICN-derived research should be.
- **Data Access**, which describes how network members can access ICN Network data.
- **Data Protection**, which describes how researchers and institutions should handle and secure ICN data.
- **Data Derivatives**, which describes restrictions and conditions on derivative products made with ICN data, such as software or statistical models.

Recommendation 17

Integrate open access and equity reviews into the request review process.

The ICN Network should leverage its registry to help realize the network's open access and equity values. This should take the form of a dedicated committee for each value and formal prompts for researchers and data requesters.

Open Access. To encourage and ensure open access, the ICN Network should request research-sharing/openness plans from researchers as part of the review process.[40] If the research was conducted in a secure data environment, the ICN Network may be in a position to help facilitate that open access: the research outputs, the tools used to produce them, and the underlying data would already be in Network custody. This can help ICN foster the positive feedback loops of research and sharing that makes learning networks so special.

Equity. Big data and machine learning can invisibly spread racial and socioeconomic biases from datasets they're based on. Research or patient datasets may be disproportionately focused on racial and demographic groups, to the exclusion of others. Inadvertently biased analysis may be deployed as part of triage and treatment algorithms, leading to disparate patient outcomes.[41] ICN could require researchers to address potential racial and socioeconomic biases or limitations in their research. In addition, the ICN Network can use priority data reviews to incentivize research that focuses on underserved patient populations.

40   *See, e.g.*, Patient-Centered Outcomes Research Institute, "Engagement Rubric for Applicants." https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf;

See also AMIA response to 2019 NIH RFC on Data Management and Sharing Policy, https://www.amia.org/sites/default/files/AMIA-Response-to-2019-NIH-RFC-on-Data-Management-and-Sharing-Policy.pdf

41   *See, e.g.*, Z. Obermeyer, B. Powers, C. Vogeli, S. Mullainathan, Dissecting racial bias in an algorithm used to manage the health of populations Science 25 Oct 2019, 447-453 ("A health algorithm that uses health costs as a proxy for health needs leads to racial bias against Black patients.") DOI: 10.1126/science.aax2342

Equitable access to resources. Patients and parents may lack time, money, and training to effectively make use of the network's resources. The ICN Network could consider requiring data requesters to describe how their work will be widely accessible by patients and parents.

Recommendation 18

Build a monitoring, enforcement, and auditing process.

Policies with no monitoring and enforcement risk being ignored. The ICN Network currently does not check whether its data sharing policies are being adhered to. While checking every request may be prohibitive, the ICN Network should establish a monitoring and auditing process to ensure that data is being handled appropriately, and that research is being shared openly.

This could be advanced with requester self-reporting. Researchers could fill out a form affirming that they have complied with the network's data policies, listing who else had access to the data they received (if anyone), and sharing work published from ICN data. External requesters or higher-risk requests could be subject to closer monitoring or mandatory audits.

The ICN Network could impose penalties for violations of data sharing policies. These could include monetary damages; restricting access to ICN data; or even removing a member from the network. This is not a recommendation for a draconian policing regime: ideally, policies help set better community norms, and help members collectively develop better data handling practices.

In addition, the ICN Network should conduct after-action reviews of select requests. Separate from the monitoring of an ongoing request, the Network can review whether it accurately assessed and mitigated the risks and benefits of a data request, or whether a request would be evaluated differently now.

Recommendation 19

Be transparent about requests for data and their dispositions.

To build trust among network stakeholders, the ICN Network should be transparent within the network about requests for data and their dispositions.

ICN Network members and stakeholders should be able to access information on requests for data: the requester, the request's content, and its disposition (whether it was approved or not). Network members should also be able to see a running list of who has access to secure data environments. Finally, the ICN Network should be transparent about its own monitoring and after-action reviews, to help Network members improve their own data handling practices.

Concessions could be made for researchers—for instance, some details of approved requests could be embargoed until publication.[42] The default should be toward transparency. This advances two goals: that the network's governance appears legitimate to its membership; and that the network can build good habits, and learn from its past decision-making.

42 *See, e.g.,* Patient-Centered Outcomes Research Institute, "Policy for Data Management and Data Sharing", September 2018, III(B)(2)(c).

Evaluating a data request

Yes

Data export?

No

Data export by outside party

Risk review + mitigation
+ stakeholder consent
+ board vote
Equity review
Open access review

Community disclosure
Post-export monitoring
+ automatic audit

Data export by network member

Risk review + mitigation

Equity review
Open access review

Community disclosure
Post-export monitoring
and random audit

In-network analysis by outside party

Secure data environment
(with access restrictions)

Risk review + mitigation
Equity review
Open access review

Community disclosure.
Elevated monitoring and
automatic audit.

In-network analysis by network member

Secure data environment

Community disclosure.

Regular monitoring and
review.

No   **Yes**

Network member?

Should the ICN Network commercialize its data?

The PDUA is ambiguous on which parties have ownership rights in the ICN Network registry. The PDUA is clear that participants don't own the combined dataset, but it lacks a definitive statement on who actually does own the ICN patient registry and its derivatives.[43]

43 CCHMC likely has the strongest claim to it.

In turn, it is not clear whose approval is required for the ICN Network to develop commercial relationships around its data. Commercial relationships may not be limited to "selling" Network data. A hypothetical relationship could see the ICN Network allowing a technology company access to registry data so that the company can develop an algorithm to predict severe disease course. The company might then freely license the algorithm to ICN Network members, and commercially license it to other customers.

This ambiguity should not be interpreted as a green light to proceed with commercial relationships. Stakeholders may see this as a violation of the network's ethos, and resist such an effort. Instead, such a decision should be taken to the stakeholder network, using a risk balancing framework recommended above.

If the ICN Network does receive money for licensing its assets, and if it decides that participants should receive royalties (as opposed to fee reductions), that should be reflected in the PDUA as consideration for participation in the network.[44] Royalties could be contingent on continued participation in the network, and calculated based on the participant's overall time in the network.

44 Including royalties for members in the bylaws could threaten ICN Inc's nonprofit status.

The ICN community

Learning networks are built to encourage collaboration and co-creation. Doctors and researchers can more easily use data to improve the quality of care. Patients and families can have a voice in what research is done and what resources are created.

One challenge to this ideal is time: doctors and researchers are already over-scheduled; patients and parents may lack time, money, and training to participate meaningfully in a network's governance without support—or to effectively make use of the network's resources.

This is ultimately an equity issue: patients with more time, money, or tech-savvy can be more active participants in the community. Those who can't may be underrepresented in the Network's research, resources, and governance.

If a family is unable to take advantage of ICN Network resources, it is a failure of the network, not the family. The ICN Network should build its community to not just connect doctors and patients, but to connect patients with life-changing resources.

This section reviews the ICN community, and makes a number of small recommendations about how to improve it.

Recommendation 20

Limit access to community and exchange data, including read-only access.

As a matter of practice, this report recommends that ICN prohibit third-party access to or data acquisition from their core community social networks. Discussion forums may contain sensitive information on patients and their families.[45] Profile data could be used to reidentify patients and parents, or to make inferences about their health. Moreover, it is technologically difficult to allow parties to access the community while preventing them from collecting data about the community. Finally, allowing third-parties access to the community in this way could be perceived as a major breach of trust, which will be difficult to repair.

To facilitate interaction between the ICN community and the outside world, the ICN Network could create sandboxed spaces explicitly for external researchers and companies. External parties would only have access to the sandboxed space, and could only interact with community members who elect to participate.

45 In addition to discussing a child's chronic disease, parents and families might lean on community networks for emotional and mental health support. *See generally* D Pickles, S Lihn, T Boat and C Lannon, A Roadmap to Emotional Health for Children and Families with chronic Pediatric Conditions, *Pediatrics,* February 2020, 145 (2) e20191324; DOI: 10.1542/peds.2019-1324

Recommendation 21

Design community platforms and resources with an equity lens.

The activities of the ICN Network have the potential to affect the well-being of thousands of patients and their families. Not every patient and family will have the time or the wherewithal to become deeply involved in the community, but it may still be an important source of low-frequency help and support.

ICN Network should consider building and evaluating its community platforms around the information needs of patients and families. A Pinterest-style layout may be a poor fit for how a patient or family is likely to access the exchange: to ask a question (which may be important but not necessarily urgent), to connect with other community members, or to find information on something specific. The current ICN Exchange appears to be little-used, is no longer supported by CCHMC, and employs out of date, insecure software.

The ICN Network should consider adopting an activity-centric design when building an Exchange replacement. Rather than merely focusing on personas, activity-centric design asks: what are the key real-world tasks that this tool is trying to facilitate?[46]

Some possible answers:

- For parents and patients, a way to ask and answer questions, and support one another.
- For parents and patients, a way to easily find resources, and to request and collaborate on new

46 *See* D Norman, "Human-Centered Design Considered Harmful", Interactions, 12. 4, (July + August, 2005). Pp. 14-19.

https://jnd.org/human-centered_design_considered_harmful/

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resources.

- For researchers, a way to engage with the ICN community.

- For the network, a way to more quickly spread best practices throughout the ICN community.

Successful community tools will make these tasks easier, and reduce the time that patients, families, and researchers need to spend searching for help. This could help expand the impact of ICN's resources beyond the most engaged members of the parent and patient community, which represent a small fraction of the total patients and parents in the ICN Network.

Secondary recommendations

Recommendation 22
Community resources should be built with public sharing in mind, even if they are not publicly shared.

Community resources should be developed as though they will be publicly shared, even if they are ultimately confined to the community. Written resources are likely to be informally shared among parents, doctors, and patients. Tracking that informal distribution is infeasible and undesirable. Moreover, because patient and parent participation in the community is a small fraction of the total patient population, designing resources to be public by default increases the likelihood that they will be widely used.

Recommendation 23
Develop a code of conduct.

The ICN Network should consider developing a code of conduct for its community (including social media). A code of conduct should be accessible to an average community member, and lay out behavior expectations for ICN Network events, social media behavior, and exchanges. This should be developed with the community.[47]

47 For resources on building a code of conduct, *see, e.g.*, K Albert, "Code of Conduct Basics and Tools", presentation to RightsCon 2018

https://docs.google.com/ presentation/d/ 1LAcnLxDsSbxmv5CVOGP5TdEkO NFlFqk_Q3vF4BF3oH4/

Recommendation 24
Amend the PDUA to clarify rules around patient contact.

The PDUA states that ICN Inc will make no effort to contact any patient who appears in the ICN database. This would seem to preclude the community of patients and parents that already work with ICN.

Recommendation 25
Clearly license community resources.

Community resources should be more consistently labeled with their Creative Commons license, which should include a link to the license itself. The ICN Network could provide an explainer for patients that details how resources are licensed and shared by default.

Recommendation 26
Post updated versions of data processes and policies.

The ICN website has outdated or incomplete data sharing polices and forms. It could also more clearly spell out the network's policies for allowing community access to new resources, such as webinars.

Recommendation 27
Provide consent controls for patients.

Consider providing tools for patients or families to provide or withdraw consent related to the ICN registry. This could also be used to reconsent patients after they turn 18.

Workshop rankings, by importance

Recommendation	Average rank	Catalina Berenblum	Chris Leff*	Inbal Kavaler	Kate Harrow	Kelsey Thome	Lisa Pitch	Mary Havens	Michael Seid	Peter Margolis	Richard Coletti	Shehzad Saeed	Steve Steiner	Traci Jester
Adopt a risk-based approach for vetting data requests. (R14)	3.33	1		9	2	5	1	2	7	1	2	3	6	1
Create a pre-approved process for network members to more easily access and analyze data, while keeping the data in network custody. (R13)	4.08	7		13	1	1	5	1	6	5	1	2	3	4
Be transparent about requests for data and their dispositions. (R19)	5.17	6		5	5	3	10	5	1	3	5	9	5	5
Formalize data sharing expectations into data sharing policies. (R16)	5.33	2		4	6	9	2	6	9	7	3	6	2	8
Increase stakeholder approval thresholds for higher-risk requests. (R15)	6.16	3		7	3	6	13	4	8	2	15	4	7	2
Build a monitoring, enforcement, and auditing process. (R18)	7.33	5		11	8	7	3	13	2	15	4	5	4	11
Amend the PDUA to clarify rules around patient contact. (R24)	7.50	11		1	11	12	7	3	3	6	7	8	14	7
Limit access to community and exchange data, including read-only access. (R20)	8.92	15		2	13	8	4	8	13	12	6	15	1	10
Integrate open access and equity reviews into the request review process. (R17)	9.50	8		10	4	10	11	12	12	4	14	7	13	9
Develop a community code of conduct. (R23)	9.83	12		12	14	15	6	15	10	9	12	1	9	3
Provide consent controls for patients. (R27)	9.83	9		3	7	11	12	7	5	10	10	14	15	15
Post updated versions of processes. (R26)	10.16	4		15	12	4	9	14	15	8	9	10	8	14
Clearly license community resources. (R25)	10.25	10		6	15	14	8	10	4	13	8	12	10	13
Design community exchange and community resources with an equity lens (R21)	10.67	14		8	9	2	14	11	11	11	13	11	12	12
Build community resources as though they will be publicly shared. (R22)	11.92	13		14	10	13	15	9	14	14	11	13	11	6

Did not submit a ranking

Implementation responsibility

Recommendation	**Recommend** Someone who brings forward a proposal or a request.	**Input** Someone who provides input to a proposal, but whose agreement may or may not be needed.	**Agree** Someone who must agree for the proposal to be carried out.	**Decide** The ONE person or body who decides and commits the network to a decision.	**Perform** Someone who executes the decision.
Create a pre-approved process for network members to more easily access and analyze data, while keeping the data in network custody. (R13)		Network membership	ICN Inc	Service Provider	Service Provider
Adopt a risk-based approach for vetting data requests. (R14)		Network membership		ICN Inc + RC	RC + Service Provider
Increase stakeholder approval thresholds for higher-risk requests. (R15)			Network membership	ICN Inc	RC + Service Provider
Formalize data sharing expectations into data sharing policies. (R16)			Network membership	ICN Inc	ICN Legal
Integrate open access and equity reviews into the request review process. (R17)				RC	RC
Build a monitoring, enforcement, and auditing process. (R18)				ICN Inc	Service Provider + ICN Legal
Be transparent about requests for data and their dispositions. (R19)				RC + Service Provider	Service Provider
Limit access to community and exchange data, including read-only access. (R20)		Patients and parents		Community team	Community team
Design community exchange and community resources with an equity lens (R21)		Patients and parents		Community team	Community team
Build community resources as though they will be publicly shared. (R22)			ICN Inc/	Community team	Community team + RC
Develop a community code of conduct. (R23)		Community members	Community members	Community team	Community team
Amend the PDUA to clarify rules around patient contact. (R24)			Member centers	ICN Inc	ICN Legal
Clearly license community resources. (R25)				ICN Inc.	ICN Legal + Community team
Post updated versions of processes. (R26)				ICN Inc.	Community team
Provide consent controls for patients. (R27)			Member centers	ICN Inc.	Service provider

3

FAQ,
enabling questions,
and recommendations

FAQ

The following questions were submitted by Digital Asset Committee members during and after the March 20, 2020 workshop.

Would honoraria for some of this work help equity?
Yes. Board members who are not health professionals could receive a honorarium, or even be directly compensated for their time and travel. This signals that ICN Inc values a director's perspective rather than merely their presence.

How often should the documentation be revisited?
Once a year. This does not mean that documentation needs to be changed every year, but the network should build a habit of regularly reviewing its core documents. An annual review process can also provide an opportunity to pass on knowledge to new or incoming leadership.

How would we involve other centers in the CCHMC role?
Involving other centers as service providers would require a clearer articulation of the specific tasks and responsibilities that CCHMC has with respect to the network. Once that happens, those tasks and responsibilities could theoretically be assigned to other centers via a Consulting Services Agreement.

Involving another center in the data management role would likely require new BAAs, or for CCHMC to assign the existing BAAs to another party.

When board terms end, how should we replace that member? Should we rotate centers, disease types, age of child, etc.?
It depends on the board member being replaced. For independent directors, a board matrix can be used as a guideline to identify needed perspectives and skills for the board. For representative board members,

there may be stakeholder-specific selection mechanisms. It may make sense to limit the presence that a single center can have on the board: for instance, a center may be limited to a maximum of one affiliated director, and an incoming director may not have the same center affiliation as her predecessor in the seat.

If the ICN Network made a profit from external data-sharing agreements, how would that be shared out?
In many cases, sharing might not happen. If ICN Inc makes a profit, that could cover operational expenses or fund new projects that align with its mission.

Member centers could see other benefits from this, such as more material support from ICN, or reduced membership fees.

In the event that royalties are distributed to member centers, ICN Inc will need to structure that distribution to avoid private inurement.

Note: this report does not take the position that ICN Inc is currently authorized to sell access to registry data to third parties.

Should we consider an Ethics Committee?
Yes. An ethics committee could provide a useful auditing and ombuds capacity that the ICN Network appears to lack right now. Committees such as these should have a mix of directors and non-directors.

Regarding Recommendation #17, should there be a mandate to disseminate information and data findings, similar to PCORI's requirements?
Yes. In general, ICN's data sharing expectations are currently framed as optional, rather than mandatory. Requiring sharing as a condition of accessing ICN's data would help advance the Network's mission.

What administrative infrastructure does ICN Inc need?
As it moves to a staffed organization with increased

responsibility for the ICN Network, ICN Inc will need to adopt financial best practices, HR policies, and other internal controls.

Resources that ICN Inc could draw on include:

• The National Council of Nonprofit Associations has produced a template employee handbook. Although it is from 2004, the handbook includes a fairly comprehensive set of HR policies.[48]

• The New York Attorney General's Charities Bureau has a brief guide on internal controls for nonprofits, and a list of practical examples.[49]

• The law firm Venable has a guide for detecting, preventing, and investigating fraud, embezzlement, and charitable diversion at nonprofits. It includes recommended preventative measures that double as good financial practices.[50]

[48] National Council of Nonprofit Associations, "Sample Employee Handbook", 2004

https://www.501commons.org/resources/tools-and-best-practices/human-resources/sample-employee-handbook-national-council-of-nonprofits

[49] New York Office of the Attorney General, Charities Bureau, "Internal Controls and Financial Accountability for Not-For-Profit Boards"

https://www.charitiesnys.com/pdfs/Internal%20Controls%20-%20Final%20-%20Small%20Type.pdf

[50] E Loya Jr, S Montaño, D Martin, J Tenenbaum, "A Primer on Detecting, Preventing, and Investigating Fraud, Embezzlement, and Charitable Diversion", 2015

https://www.venable.com/files/Publication/1df8ab63-6f13-48d2-984a-38ebfe30d0ba/Presentation/PublicationAttachment/c0ea21eb-372e-4bc0-a99c-5674d384bf2a/A-Primer-on-Detecting-Preventing-and-Investigating-Fraud-Embezzlement-and-Charitable-.pdf

Recommendations

1. Clarify the contractual relationships between ICN Inc., Cincinnati Children's, and the ICN Network.

2. Amend the Consulting Services Agreement to clarify rights and responsibilities between ICN Inc and Cincinnati Children's.

3. Grant ICN Inc. more agency over the ICN Network's IP.

4. ICN Inc. should modify its bylaws to formally reserve seats for representatives of key network stakeholder groups.

5. ICN Inc. board members should have terms and term limits.

6. ICN Inc. could adopt membership and create community-driven systems for electing board members.

7. ICN Inc. should formalize its councils and working groups, and use them as a governance resource.

8. ICN Inc. should establish a more robust conflict of interest policy that accounts for non-financial conflicts of interest.

9. ICN Inc. should create committees with data-related responsibilities.

10. ICN Inc. should create an equity committee.

11. ICN Inc. should create whistleblower and document retention policies.

12. ICN Inc. should create a network continuity plan.

13. Create a pre-approved process for network members to more easily access and analyze data, while keeping the data in network custody.

14. Adopt a risk-based approach for vetting data requests.

15. Increase stakeholder approval thresholds for higher-risk requests.

16. Formalize data sharing expectations into data sharing policies.

17. Integrate open access and equity reviews into the request review process.

18. Build a monitoring, enforcement, and auditing process.

19. Be transparent about requests for data and their dispositions.

20. Limit access to community and exchange data, including read-only access.

21. Design community exchange and community resources with an equity lens.

22. Build community resources as though they will be publicly shared.

23. Develop a community code of conduct.

24. Amend the PDUA to clarify rules around patient contact.

25. Clearly license community resources.

26. Post updated versions of processes.

27. Provide consent controls for patients.

Enabling questions

Below are key questions that ICN Inc and Cincinnati Children's need to answer in order to implement the recommendations outlined in this report.

- Should ICN Inc be the independent steward of the ICN Network?

- Should ICN Inc be included in the registry chain of custody?

- Who should assume the responsibilities assigned to the Network pseudo-entity?

- What IP rights should ICN Inc and Cincinnati Children's have with respect to materials developed under the Consulting Services Agreement?

- What roles do each ICN Inc and Cincinnati Children's play in executing key Network tasks?

- Who should be on the board? How should board members be selected? What stakeholder groups should be represented?

- What committees should ICN Inc. have? What should their rules and responsibilities be? What should their membership be?

- What should be the prerequisites for pre-approved access to an ICN Network secure data environment?

- What risks should a data review process focus on? Who should be involved in evaluating each risk?

- How should the data review forms change?

- What scenarios should the ICN Network use to stress-test its data review process?

- Should the ICN Network allow third-party access to its data?

- What values should the ICN Network promote and enforce via its data request process?

- How quickly will the ICN Network share information about data requests and their dispositions?

- How should data requests be monitored after the fact?

- What penalties should be imposed for violations of ICN data policies?

- How can the ICN Network ensure equitable development, access, and adoption of its resources?

- Why does the ICN Exchange exist? How will we know if it is successful?

- What other values should the Network be actively promoting in its data review process?

- How should the data review forms change?

- Who should be allowed in the ICN community?

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APPENDIX
Worksheets

RAPID worksheet

Task	Recommend Someone who brings forward a proposal or a request.	Input Someone who provides input to a proposal, but whose agreement may or may not be needed.	Agree Someone who must agree for the proposal to be carried out.	Decide The ONE person or body who decides and commits the network to a decision.	Perform Someone who executes the decision.
Admit new members.					
Set terms of membership. (fee, rules, etc)					
Host and manage patient registry data					
Handle requests for patient registry data.					
Set, monitor, and enforce data access terms.					
Manage HIPAA compliance for registry data.					
Handle cybersecurity and risk management for registry data.					
Report improper use of registry data.					
Store research derivatives.					
Make research and resources available.					
Change network data sharing policies.					
Create community resources and assets.					
Host and manage community resources and non-registry assets.					
Permit access to the ICN Community.					
Manage and monitor the ICN Community.					
Handle compliance for the ICN Community.					
Handle cybersecurity and risk management for the ICN Community.					
Change ICN Community policies.					
Collect new data from patients.					
Collect new data from members.					

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RAPID worksheet

Task	**Recommend** Someone who brings forward a proposal or a request.	**Input** Someone who provides input to a proposal, but whose agreement may or may not be needed.	**Agree** Someone who must agree for the proposal to be carried out.	**Decide** The ONE person or body who decides and commits the network to a decision.	**Perform** Someone who executes the decision.

Board composition worksheet

Stakeholders	Board Seats	Term	Term limit	Method of selection
Patients				
Parents/Families/Guardians				
CCHMC				
Physicians/Clinical teams				
Multidisciplinary professionals				
Legal/Financial Institutional leadership				
Independent directors				

Board-level committees	Skills needed	Diversity measures

Committee composition worksheet

Committee: _____

Stakeholders	Seats	Term	Term limit	Method of selection