Consent Policy Design Group

Meeting #3
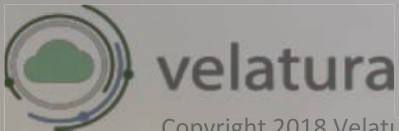*May 7, 2019*

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Office of Health Strategy

Agenda

Agenda Item	Time
Welcome & Introductions	1:00 pm
Public Comment	1:05 pm
Use Case Approach to Sharing Health Data	1:10 pm
Overview of May 21, 2019 Meeting	1:55 pm
Wrap-up and Meeting Adjournment	2:00 pm

Use Case Approach to Sharing Health Data

Dr. Tim Pletcher

Dr. Lisa Moon

Objectives

- Provide foundational principles of data sharing in a community through push and pull mechanisms

- Describe how Use Cases support predictable data sharing in health care ecosystem like Connecticut

- Give examples to demonstrate how these concepts work together

- Explain the connection between legal data sharing agreement and public transparency created through governance

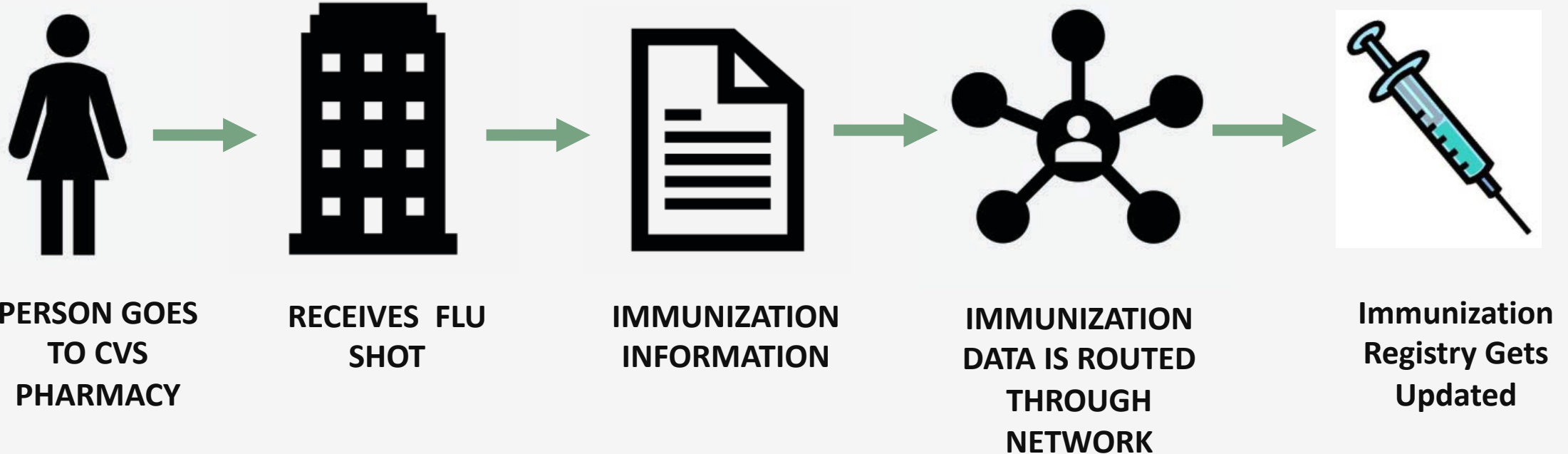- Outline how we plan to baby step through this complicated space

First Let's Discuss Ways to Get Data

1) Data comes to you or gets "pushed"

   a. A special kind of "push" scenario is called an "**Alert**"
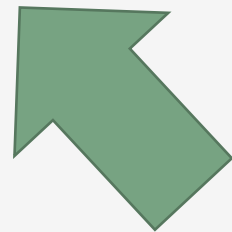
2) You request or "pull" data from a known location

Pushing Data to One Known Endpoint

Immunization

PERSON GOES TO CVS PHARMACY → **RECEIVES FLU SHOT** → **IMMUNIZATION INFORMATION** → **IMMUNIZATION DATA IS ROUTED THROUGH NETWORK** → **Immunization Registry Gets Updated**

Pushing Data to a Specific Endpoint

Consent & Patient Matching Decisions Are Made Here

Encounter Notification Example of Alert
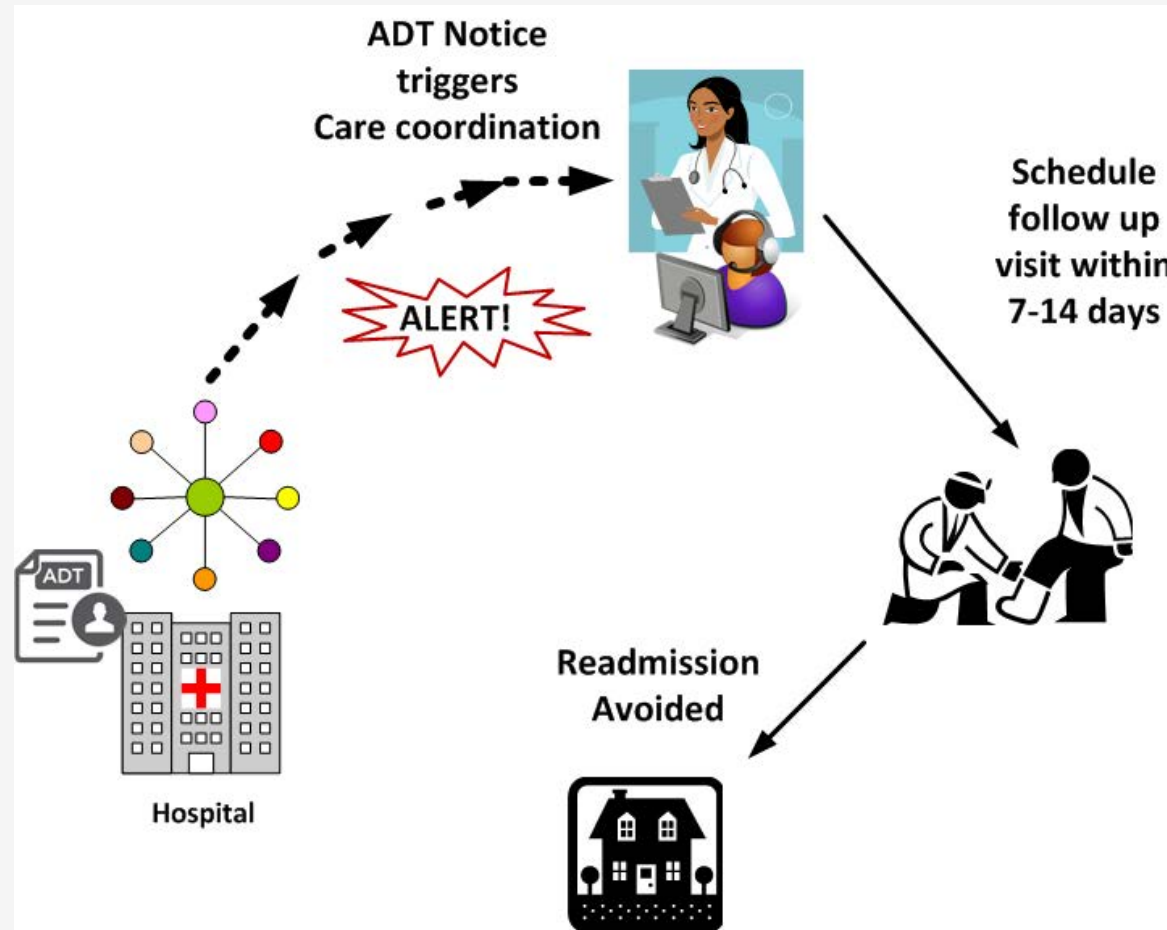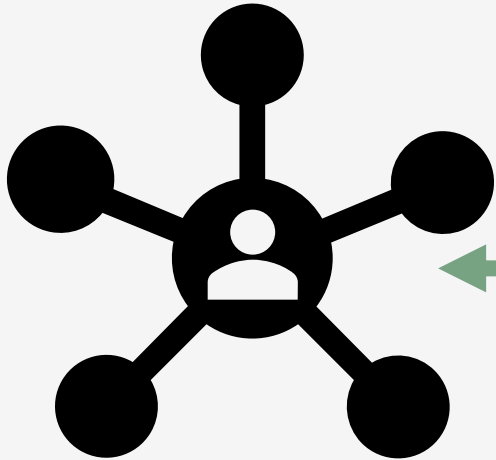
Pushing Data to Multiple Endpoints
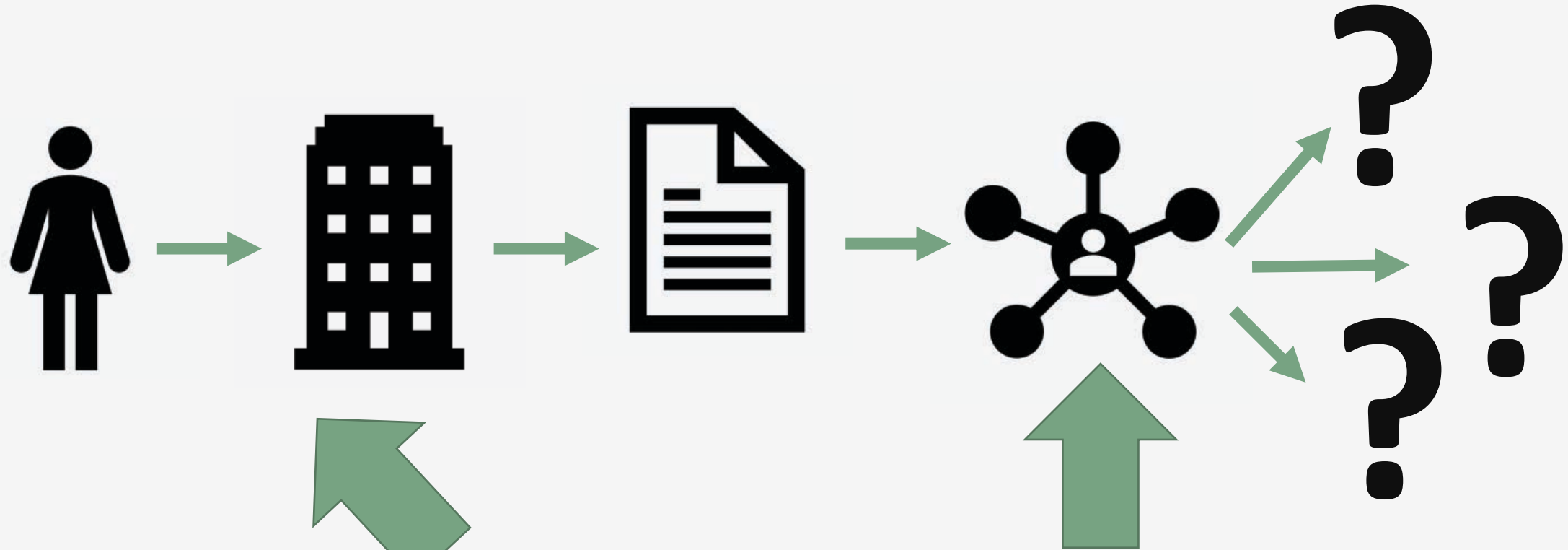
Consent Decision
Is Made Here

Important Decisions
Are Also Made Here
If Sent to Multiple
Places

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The HIE Continuum

Network of Networks

Longitudinal Medical Record

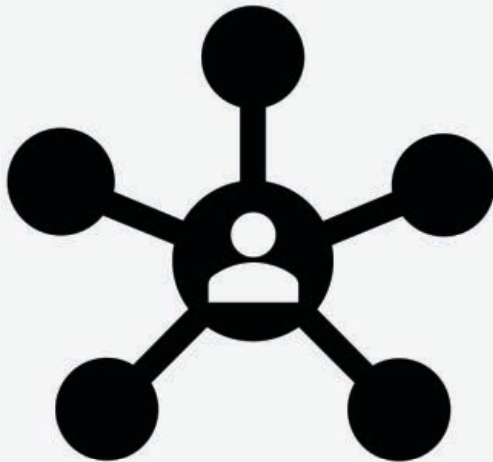**The HIE only Routes or Brokers Requests Among Participants**

A Copy of All the Data Resides In the HIE

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Benefits of a Network of Networks

Network of Networks

The HIE only Routes or Brokers Requests Among Participants

- Organizations tend to trust this model more because the HIE does not keep a pile of data that might be used for unintended purposes or be a cyber security risk

- Often less costly because they allow the data to be maintained at the source

- Generally, easier to make progress as there are lower expectations and concerns

- More like how the Internet works so more "future proof" in a world moving toward a web of interoperable systems

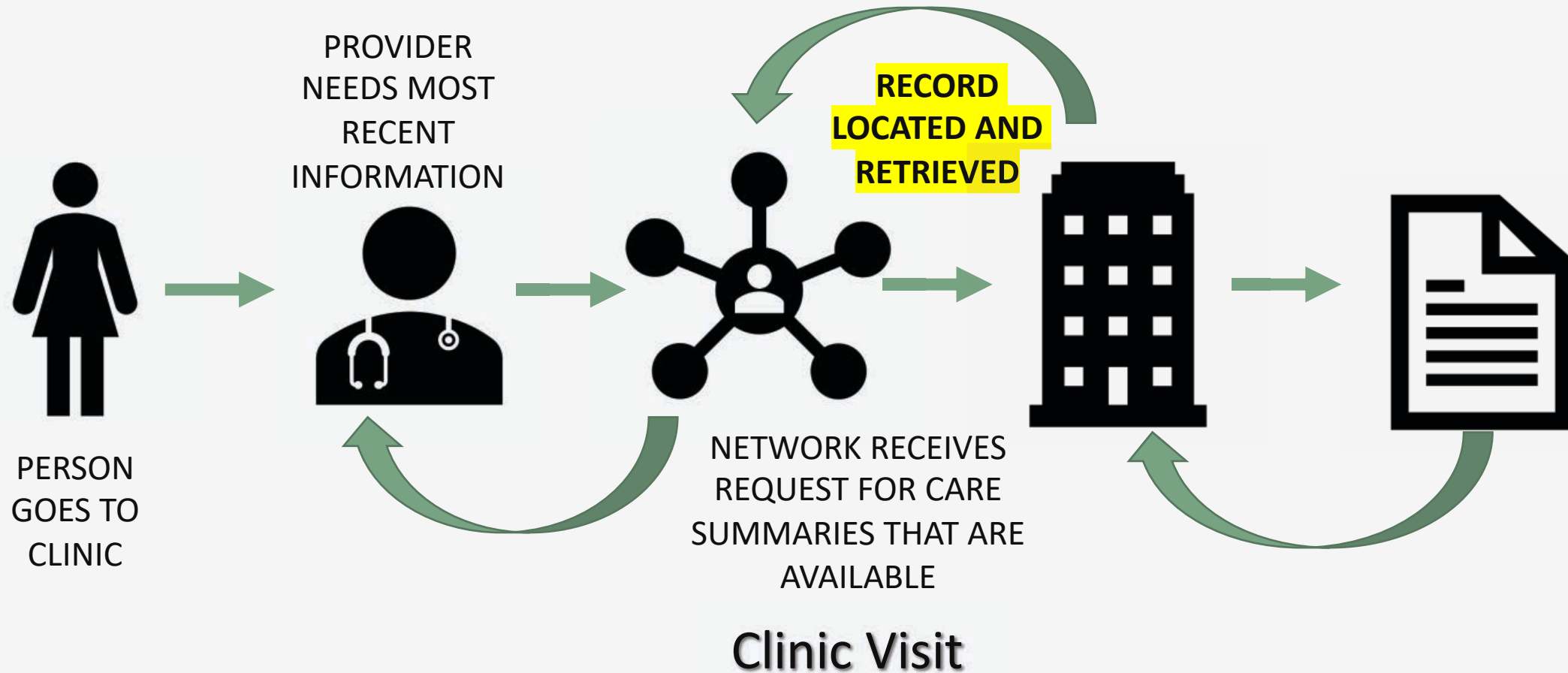# Benefits of a Longitudinal Record

Longitudinal Medical Record
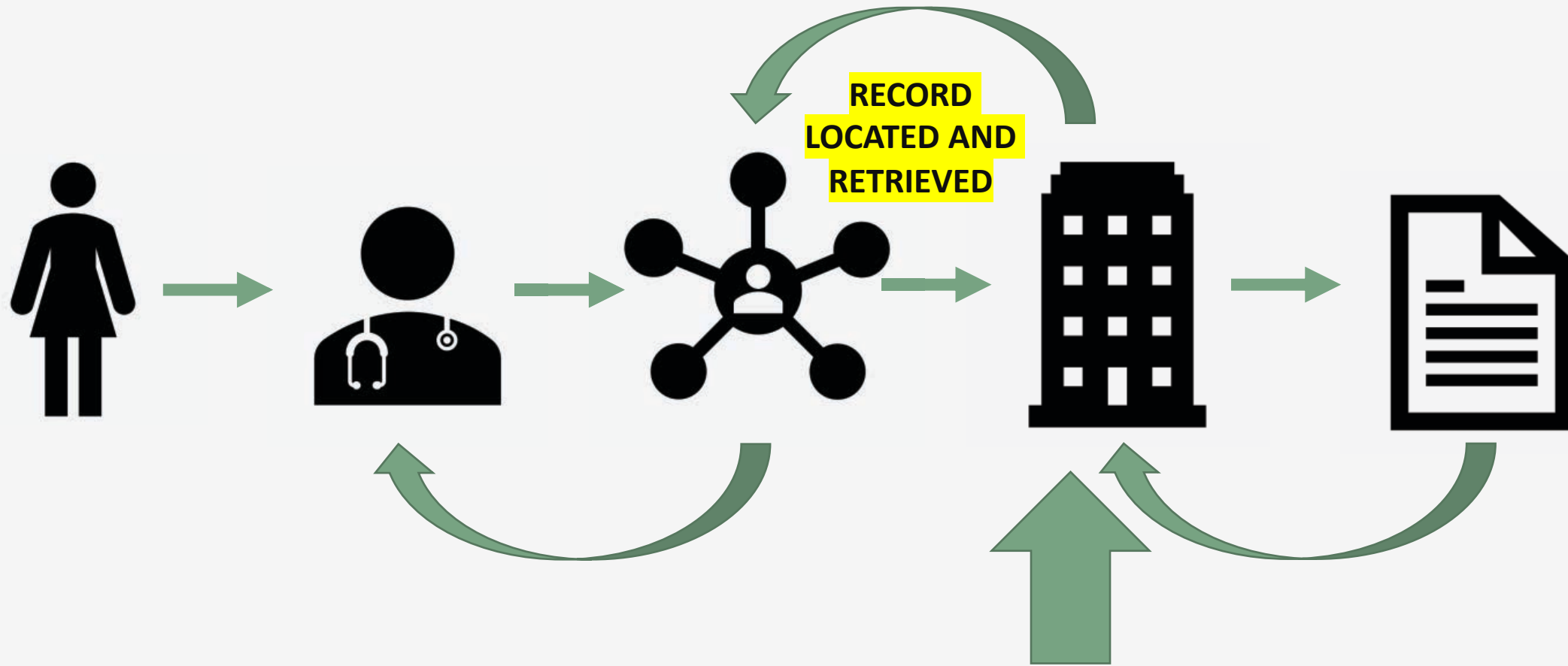

- Once everyone participates, it simplifies where to go for data

- Data is already available for new uses not previously envisioned

- Ability to do advanced analytics on the data

Pulling Data from an Endpoint

PROVIDER NEEDS MOST RECENT INFORMATION

RECORD LOCATED AND RETRIEVED

PERSON GOES TO CLINIC

NETWORK RECEIVES REQUEST FOR CARE SUMMARIES THAT ARE AVAILABLE

Clinic Visit

Pulling Data Is More Complicated

RECORD LOCATED AND RETRIEVED

Consent & Patient Matching Decision Are Made Here

Pulling Data Continued
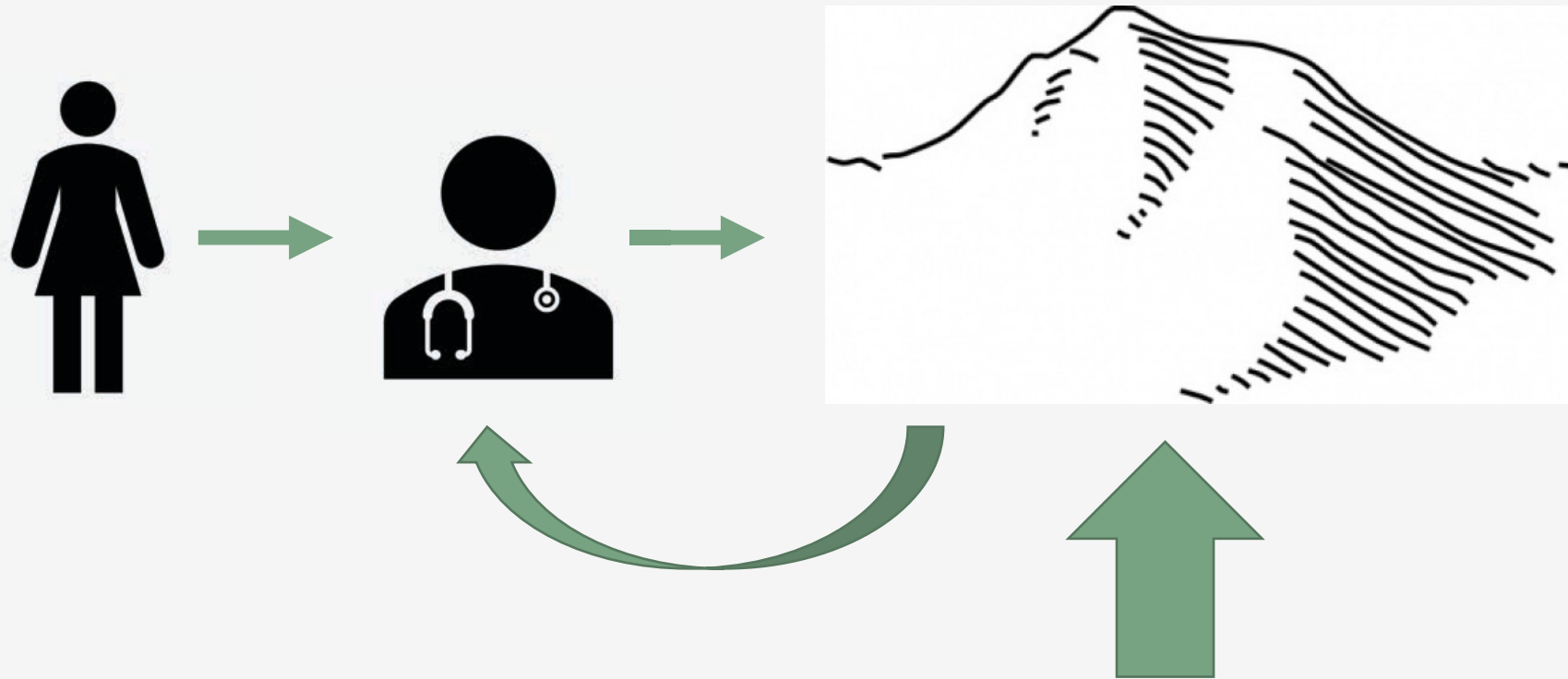
Consent & Patient
Matching Decisions
Are Made Here

Summary

- Pushing data to one well known place is easy
- Pushing data from one place to multiple places is a little more complicated but the data source has a lot of control especially if the "subscribers" to the patient are discoverable
- Pulling data gets more complicated
  - Do we even know where to pull the data from?
  - Is everyone involved confident the patient matching is accurate?
  - How does the entity getting the request to release the information know the organization making it has consent?

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Small Bites
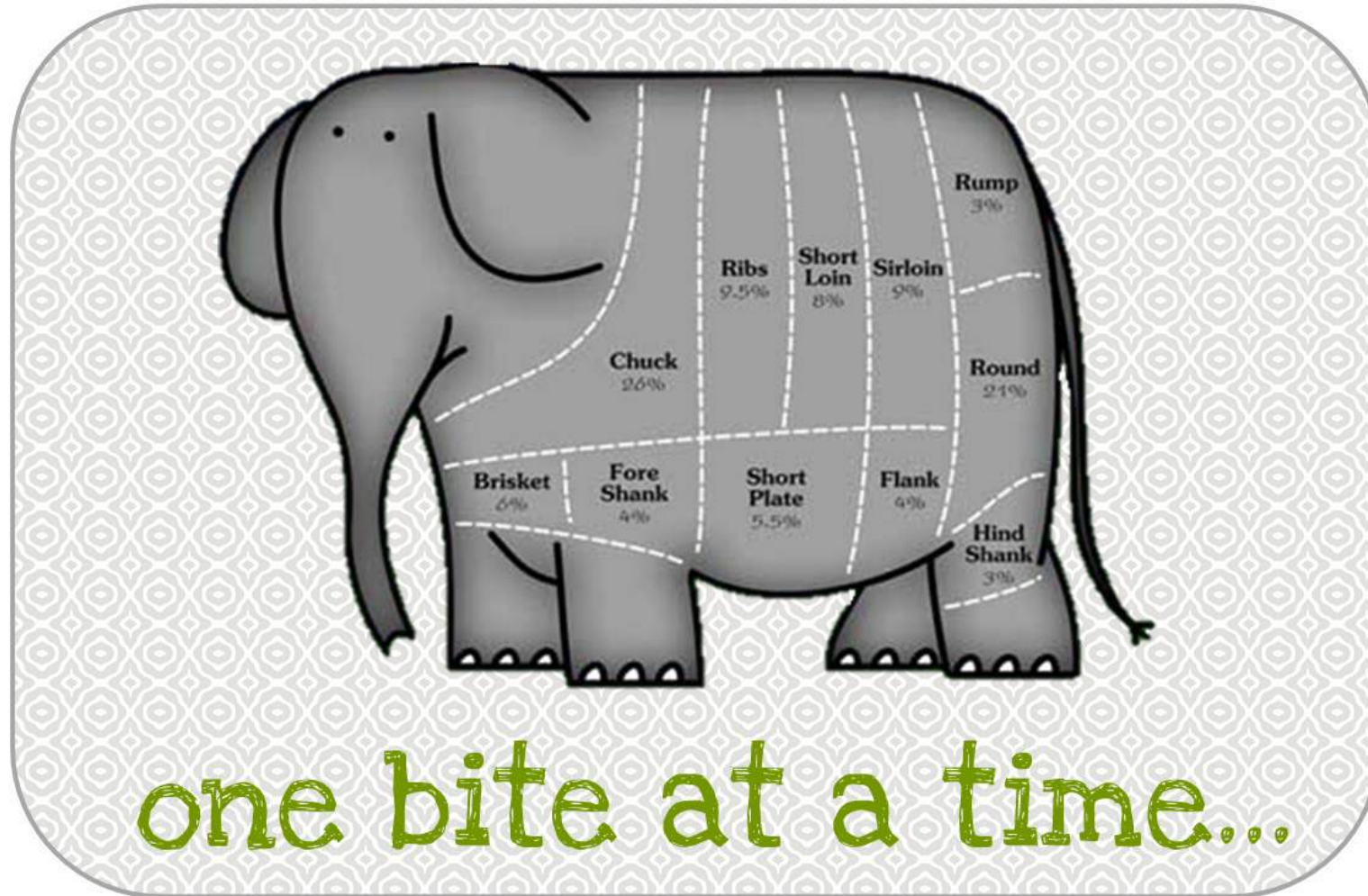
"Network of Networks" Model
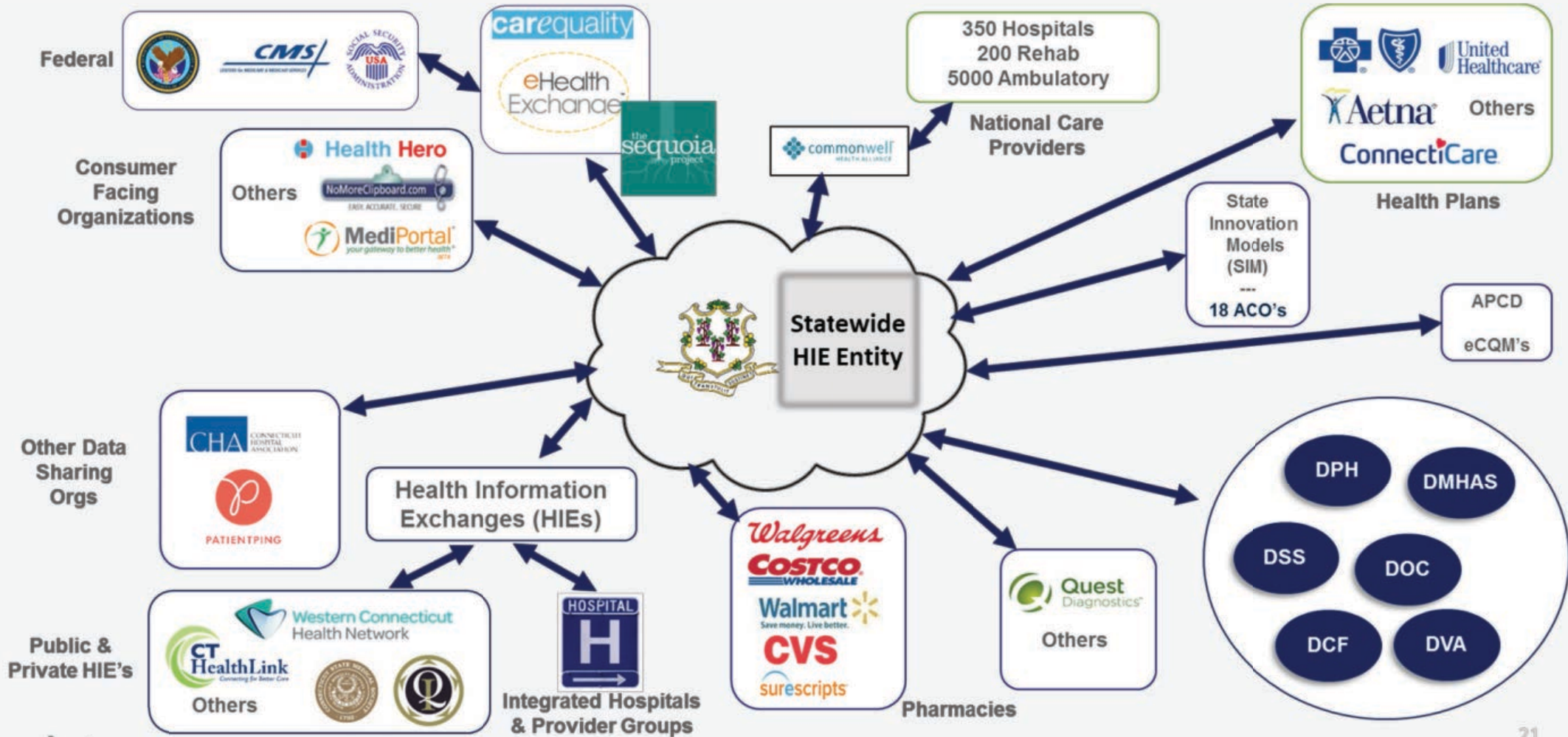
Steps to Legally Connect to the HIE

Step One: Execute one of the following agreements to join the network:
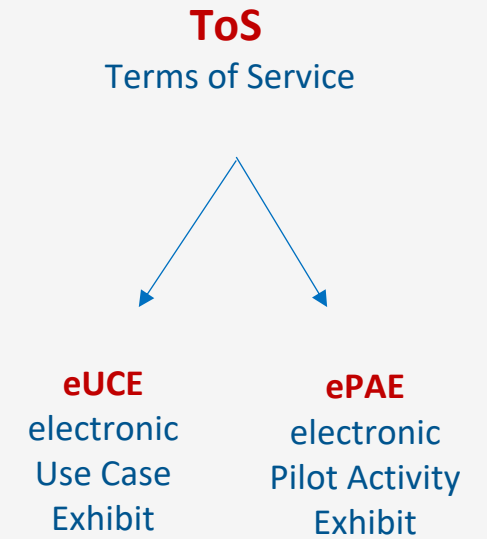(1) Qualified Data Sharing Organization Agreement (QDSOA) **or**
(2) Simple Data Sharing Organization Agreement (SDSOA) **or**
(3) Terms of Service (ToS)

Step Two: Execute Use Case Exhibits (UCEs) to share information

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Trusted Legal Framework

QDSOA
Qualified Data Sharing
Organization Agreement

HIE
Governance

UCE
Use Case
Exhibit

PAE
Pilot
Activity
Exhibit

SOW
Statement
of Work

SDSOA
Simple Data Sharing
Organization Agreement

UCE
Use Case
Exhibit

PAE
Pilot
Activity
Exhibit

SOW
Statement
of Work

ToS
Terms of Service

eUCE
electronic
Use Case
Exhibit

ePAE
electronic
Pilot Activity
Exhibit

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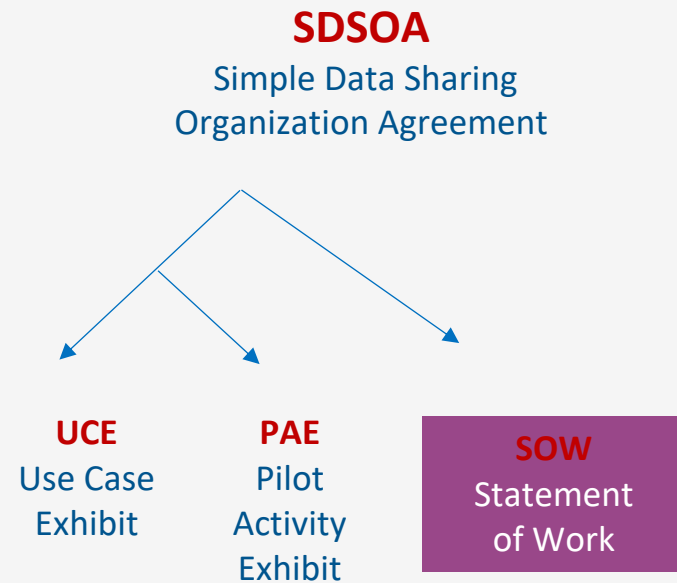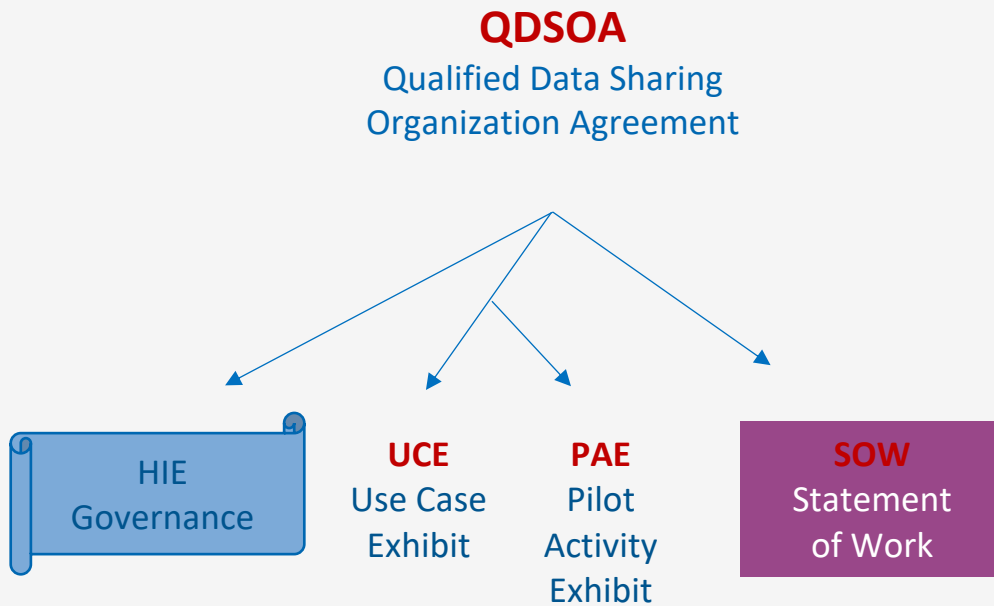
Trusted Legal Framework

JOIN NETWORK

Organization Agreement (QDOSA, SDSOA)

Definitions
HIPAA Business Associate Terms
Contracting & Payment
Cyber Liability Insurance
Indemnification & Liability
Basic Connection Terms & SLA
Dispute Resolution
Term & Termination

SHARE DATA

Master Use Case Agreement

Use Case #1	Use Case #2	Use Case #3		Use Case #N

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Break-Bulk Shipping

Modern Container Shipping

Large Use Cases Identified

Wave 1 Use Cases and Associated Tasks

eCQM	• Procurement and implementation
IIS (Submit/Query)	• Implementation and integration with Public Health Reporting; procurement
Longitudinal Health Record	• Leverage eHealth Exchange, CareQuality, and CommonWell • Implement core services (e.g. master person index and health provider directory)
Public Health Reporting	• Assess potential to leverage/expand AIMS • Implement expanded data elements, onboarding, and technical assistance
Clinical Encounter Alerts	• Finalize business and functional requirements • Procurement / contracting (including leverage existing assets)
Image Exchange	• Finalize business and functional requirements • Further discussions with NYeC and other image sharing networks

Wave 2 Use Cases and Associated Tasks

Medical Reconciliation	• Implement program for process re-design and supporting technology
MOLST / Advance Directives	• Partner with existing MOLST Task Force and Advisory Committee for assessment of technology value-add and the value of a complimentary AD Registry
Patient Portal	• Plan for rollout after implementation of longitudinal health record
Population Health Analytics	• Plan for rollout after eCQM reporting

Future Use Cases

Bundle Management	Lab Results Delivery
Care Coordination: Care Plan Sharing	Life Insurance Underwriting
Care Coordination: Referral Management	Medical / Lab Orders
Care Coordination: Transitions of Care	Medical Orders / Order Management
CHA Dose Registry	Opioid Monitoring and Support Services
Disability Determination	Patient-generated Data
eConsult	Research and Clinical Trials
Emergency Department Super-utilizers	Social Determinants of Health
Emergency Medical Services (EMS)	Wounded Warriors
Genomics	

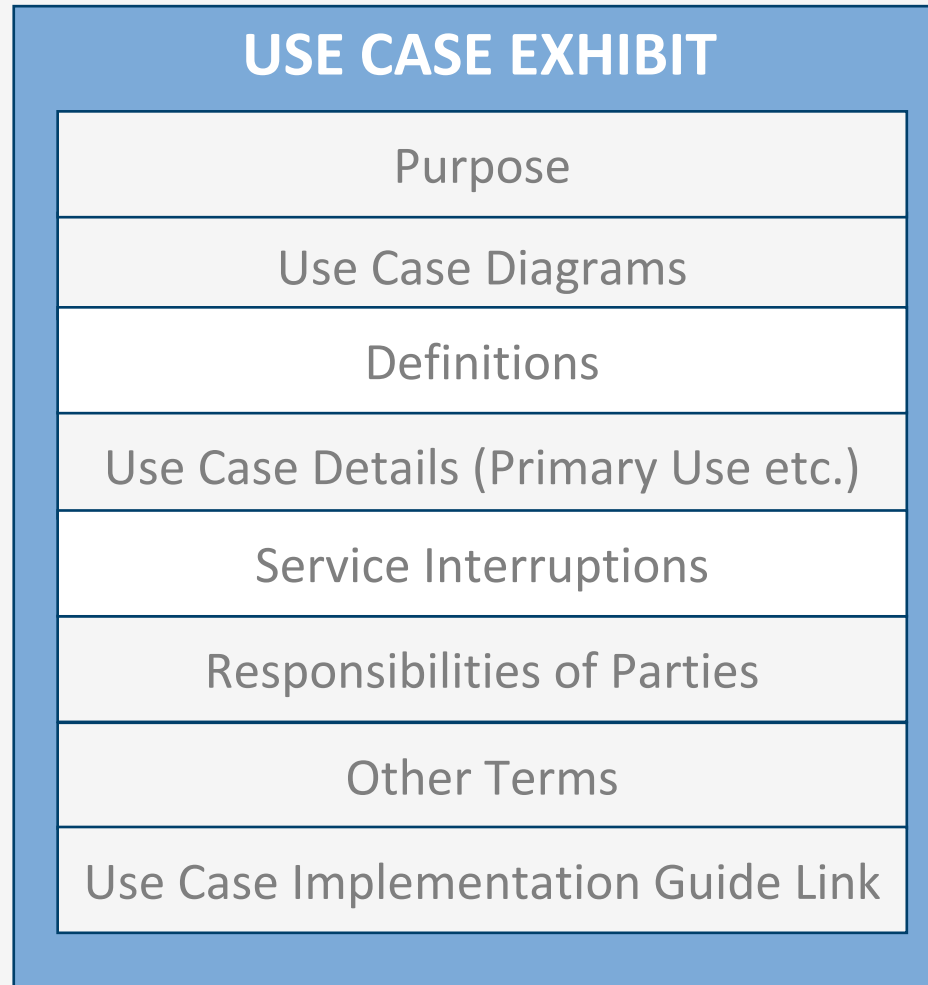velatura

What are Use Cases?

- Data sharing scenarios with defined purpose, type of data exchanged, and interactions between systems
  - Admission, Discharge or Transfer Notification
  - Immunization Transaction
- Includes business, technical, and legal framework for sharing the data

Use Case Components:

- Use Case Summary
- Use Case Legal Exhibit
- Technical Implementation Guide
- Onboarding Documentation

Components of a Use Case Exhibit

USE CASE EXHIBIT
Purpose
Use Case Diagrams
Definitions
Use Case Details (Primary Use etc.)
Service Interruptions
Responsibilities of Parties
Other Terms
Use Case Implementation Guide Link

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Use Case Exhibit Example

USE CASE EXHIBIT

Purpose
Use Case Diagrams
Definitions
Use Case Details (Primary Use etc.)
Service Interruptions
Responsibilities of Parties
Other Terms
Use Case Implementation Guide Link

Use Case Exhibit Example, Cont'd

The document on the left reads:

3. **Definitions.** Capitalized terms used herein and not otherwise defined, shall have the meaning given them in the MUCA and the Data Sharing Agreement.

    3.1. **Message Content** means Consolidated Clinical Document Architecture (C-CDA) messages (see UCIG for specifications).

    3.2. **Transactional Basis** means sending Message Content or a Notice from a sending or receiving party. A transaction is a single Message. Only if HIN and PO mutually agree in writing, PO shall be allowed to send/receive files containing multiple messages.

4. **Use Case Details.** Message Content pursuant to this UCE may be sent, received, found or used as follows:

    4.1 **Primary Use**

    4.1.1 HIN will receive Message Content from a sender, determine care relationships based upon the Active Care Team found in the Continuum of Care and Consent Map, and send the Message Content and related Notices to providers based upon routing, destination and delivery preferences.

    4.1.2 The Message Content may be used by Health Professionals for Treatment, Payment and/or Healthcare Operations consistent with the requirements set forth in HIPAA.

    4.2 **Additional Permissible Use**

    4.2.1 Message Content may be used such as for resolution of patient matching in support of other HIN Infrastructure Services including but not limited to the Common Key Service working in conjunction with the CCCM and related MPI support.

    4.2.2 Message Content may be used to notify eligible patients or guardians.

    4.2.3 The following sections of the MUCA are not permissible uses under this Exhibit: 4.2.7 ("Pilot Activities").

    4.3 **Limitations on use** Message Content may not be used for competitive purposes. PO may send, receive, find, or use Message Content consistent with the terms herein and as otherwise permitted by the Agreement, *provided, however,* that in no case shall PO share Message Content in a manner inconsistent with this UCE, as applicable.

    4.4 **Related Use Case Requirements** In addition to the Use Cases required under the MUCA, PO must utilize the CCCM Use Case.

5. **Service Interruptions.** No variations identified.

USE CASE EXHIBIT

- Purpose
- Use Case Diagrams
- Definitions
- Use Case Details (Primary Use etc.)
- Service Interruptions
- Responsibilities of Parties
- Other Terms
- Use Case Implementation Guide Link

Use Case Exhibit Example, Cont'd

6. Responsibilities of the Parties.

6.1. PO's Responsibilities as a Sender

6.1.1. PO shall ensure that Message Content is a Conforming Message and is properly encoded and can be properly parsed. In particular, information about the Health Provider must be valid.

6.1.2. PO agrees that any TDSO and their participants that have an ACR with a particular patient may receive the Message Content for that patient except in the case of a self-paid service where the patient has requested that no Patient Data be sent to Health Plans.

6.2. PO's Responsibilities as a Recipient

6.2.1. PO shall send to HIN Services any Notices received from PO, as necessary (*e.g.*, sending an acknowledgment of Message Content received from PO).

6.2.2. PO and its PO Participants that receive Message Content shall work with HIN to update and maintain the required information per the CCCM Use Case and the Master Provider Registry (MPR).

6.3. HIN's Responsibilities

6.3.1. HIN shall send to PO and other TDSOs and their PO Participants which have an ACR with the patient all Conforming Messages received from a TDSO and Notices in a consistent manner on a Transactional Basis or in batches.

6.3.2. HIN shall send the Message Content it receives to those TDSOs having any non-expired ACR with the patient identified in Message Content, provided that HIN shall not send Message Content to any TDSO or their PO Participants that have not updated their CCCM data at least once within the previous ninety (90) days.

6.3.3. HIN shall retain all Message Content after receipt for up to ninety-one (91) days unless subject to a litigation hold.

6.3.4. HIN may send Message Content containing a Health Plan designation within the Message Content to a Health Plan TDSO ("Payer TDSO") except HIN shall not send Message Content to any Health Plan(s) if the Message Content indicates self-paid as defined in the UCIG.

6.3.5. HIN shall work with PO and/or its PO Participants who are recipients to receive and process updates per the CCCM Use Case.

7. Other Terms.

USE CASE EXHIBIT

Purpose
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Use Case Exhibit Example, Cont'd

USE CASE EXHIBIT

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Benefits of Use Case Approach

Reduces Complexity	Manageable chunks so competitive or confidentiality concerns can be addressed without "boiling the ocean"
Consistent Pattern	Standardized mechanism for scoping purpose, technical requirements, costs, and limits on how data is used
Modular (like Containers)	Use Cases can be combined to create more extensive stories for data sharing
Aligns Priorities	Incentives, regulations or policies can target specific Use Cases to foster or accelerate adoption
Transparent	Constituents can understand expected use of their data and follow common chain of trust across organizations
Measureable	Aids focused monitoring and measurement of progress
Faster & Cost Effective	Reduces variability and enables scalability

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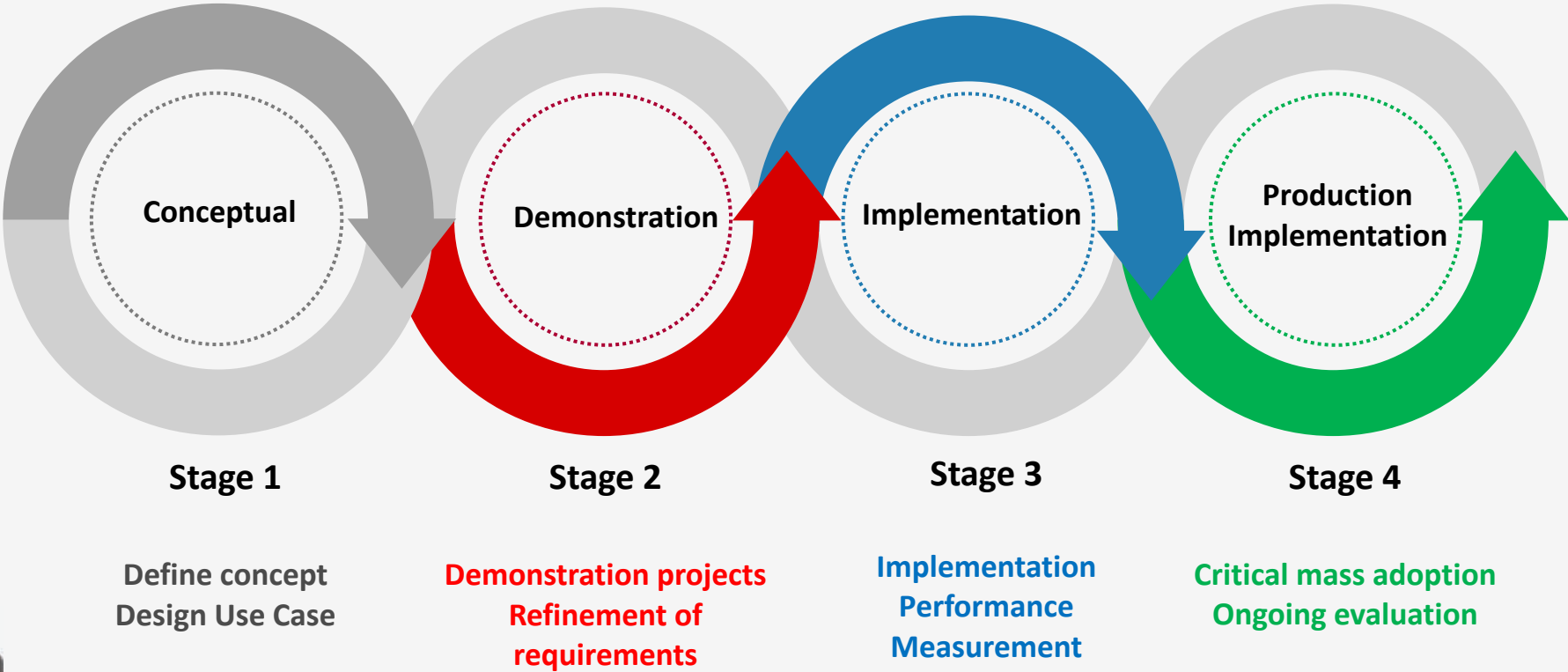# Who ensures that Rules of the Road are followed?

Typically the Health Information Network relies on a **three levels** of governance

1. State Health Information Technology Advisory Committee
2. Health Information Network Board
3. Operational Governance Committees

Use Case Factory™ – Predictable Data Sharing
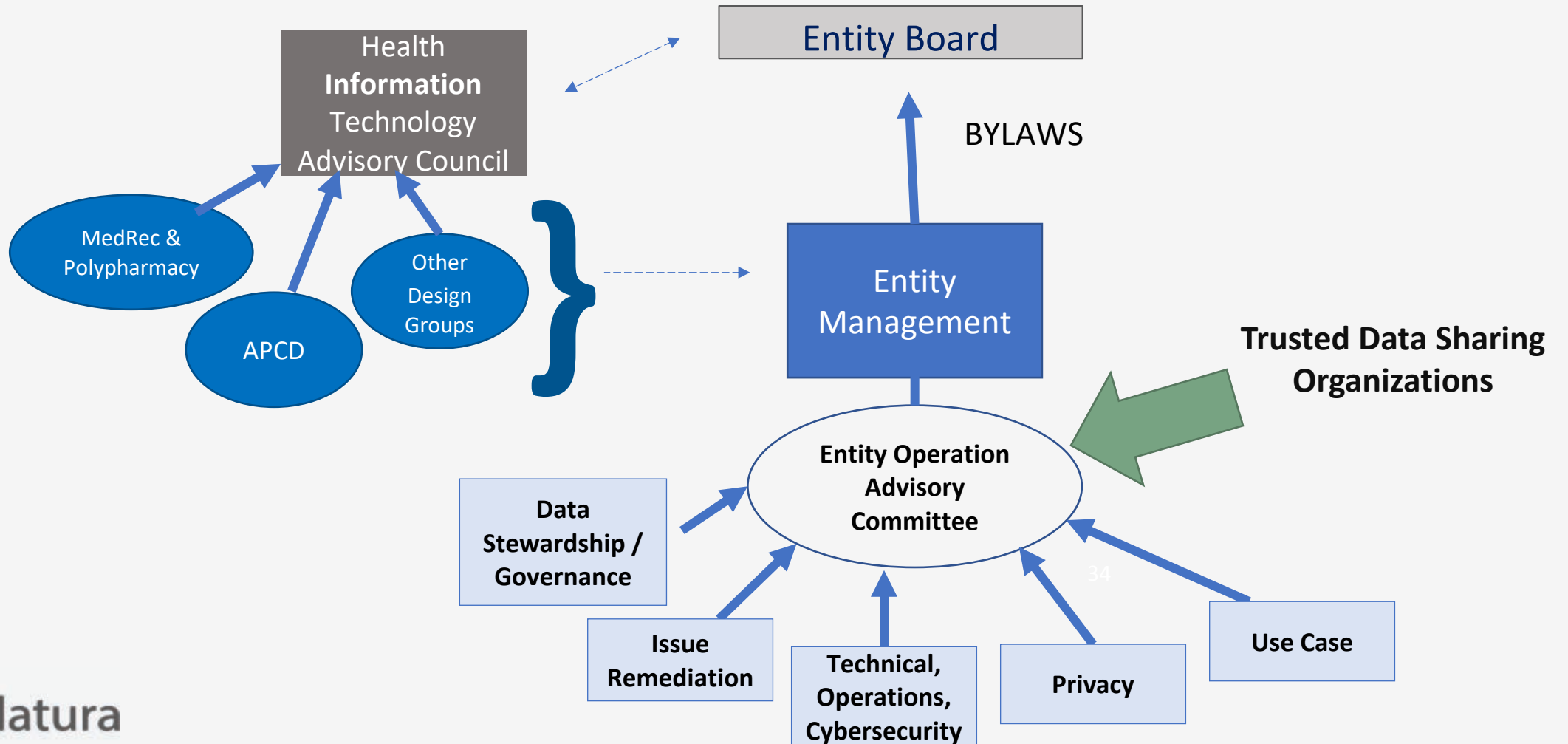
Conceptual	**Demonstration**	**Implementation**	**Production Implementation**
Stage 1	**Stage 2**	**Stage 3**	**Stage 4**
Define concept Design Use Case	Demonstration projects Refinement of requirements	Implementation Performance Measurement	Critical mass adoption Ongoing evaluation

Public Transparency

Operational Governance
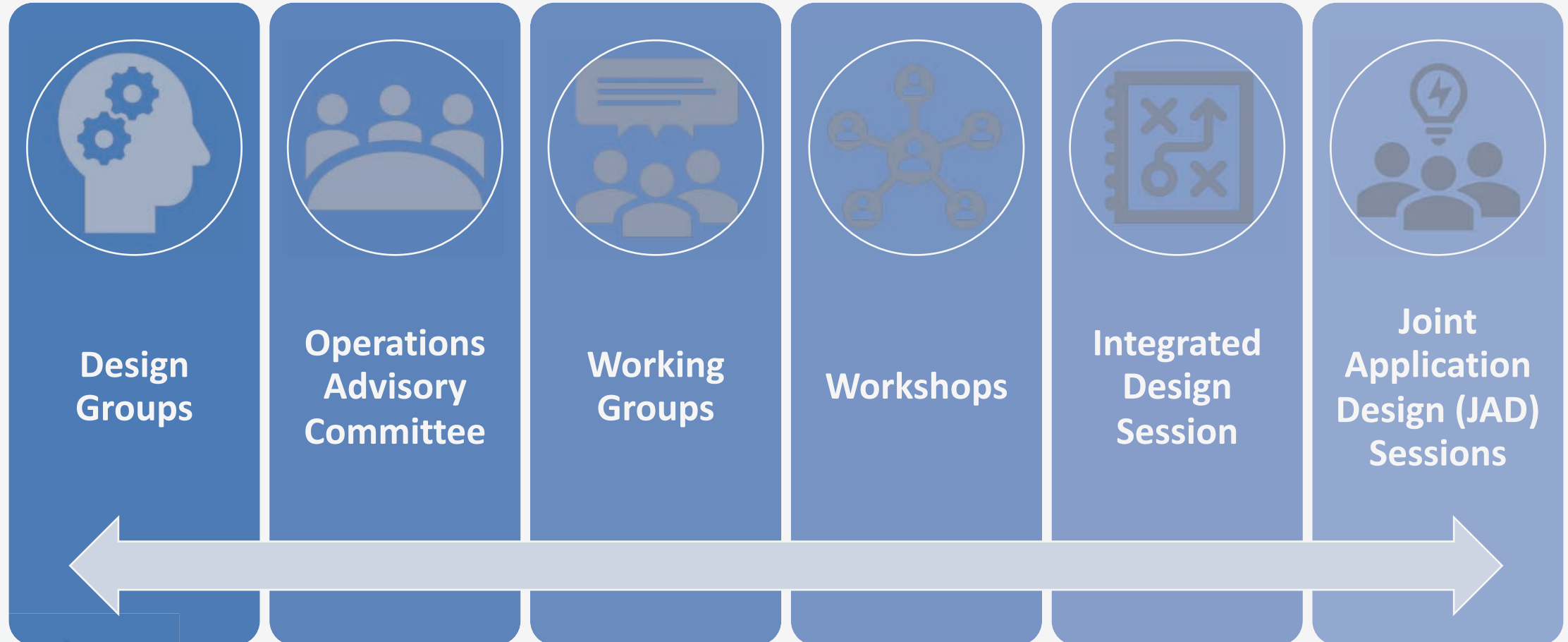
Design Groups	Operations Advisory Committee	Working Groups	Workshops	Integrated Design Session	Joint Application Design (JAD) Sessions

Flow of Use Case Information between Groups

Health IT Advisory Council charters Design Groups

Group identified in Workshop, Seminar, Working Group, etc.

Design Group

Entity Management

SLA

AIMS

Entity Operation Advisory Committee

JAD Session

Workshop Series

Service functionality & Business Requirements

Use Case Pilot Activities

Working Groups

Technical, Operations, and Cybersecurity

Integrated Design Session

Pilot to Production

Use Case Factory
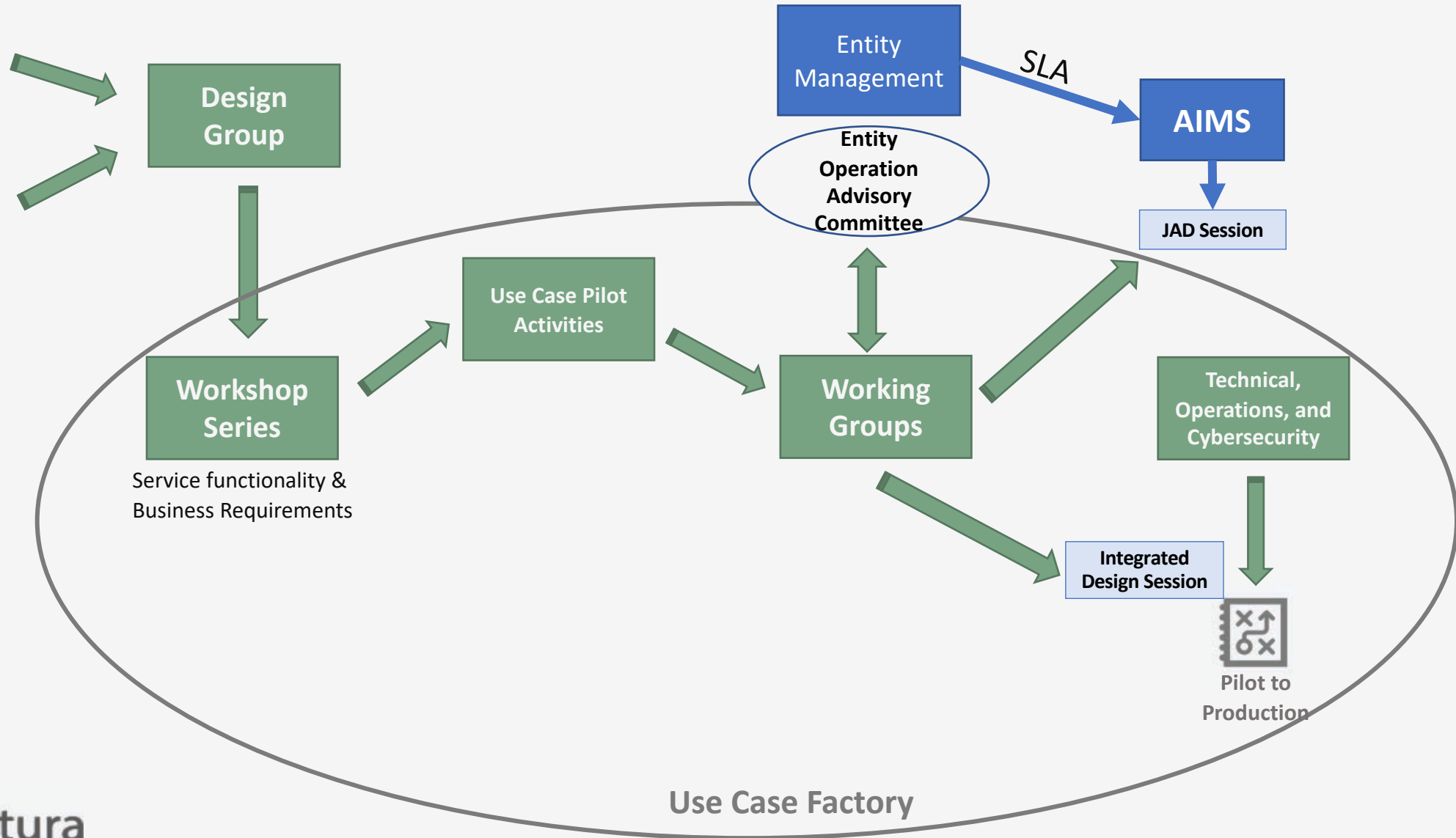
HIE Trust Framework Governance Model
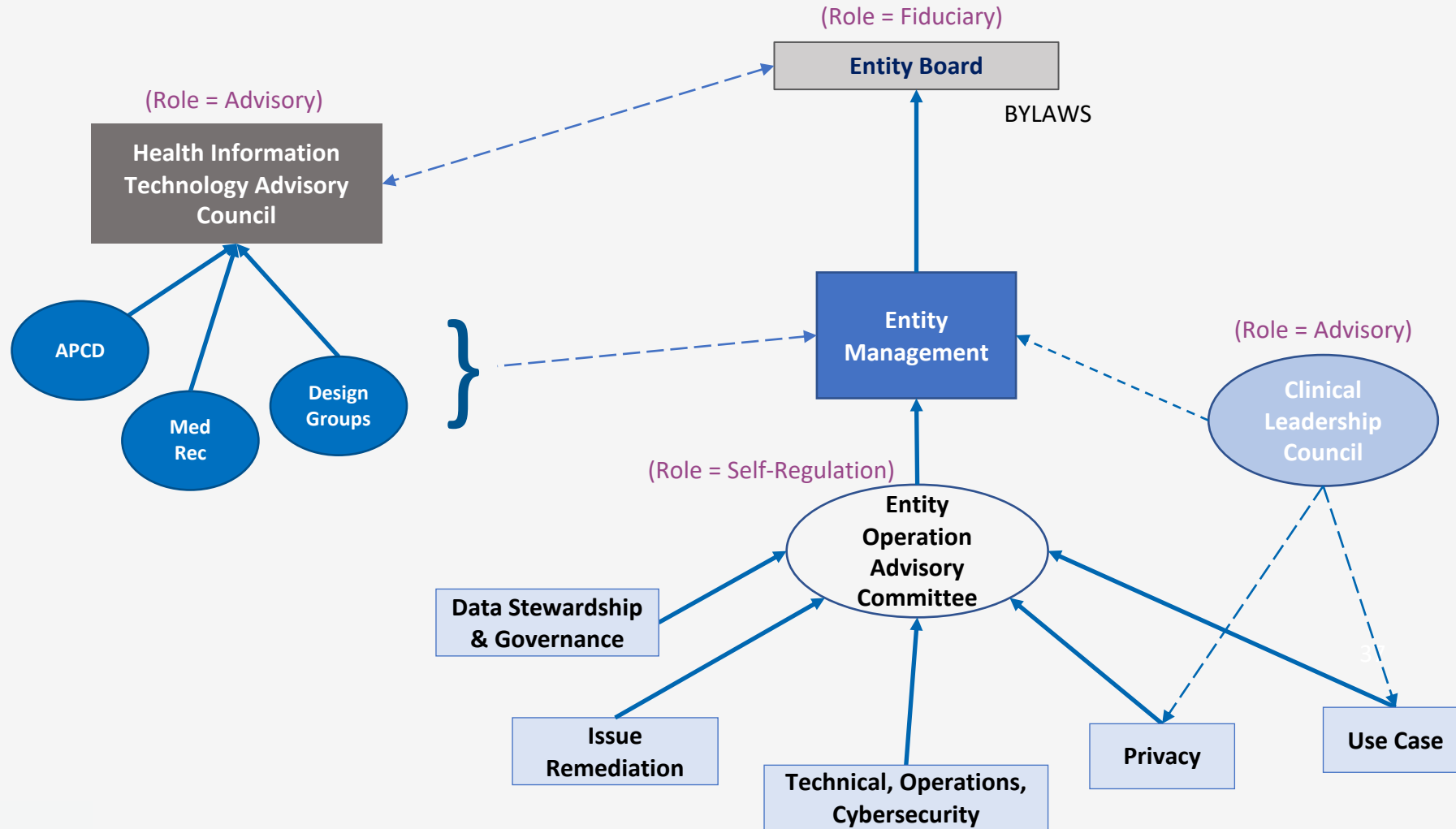
Dispute Resolution Process

Applies for disputes between two TDSOs or between a TDSO and the HIE Entity

1. TDSO or HIE will send written notice of concerns to the Issue Remediation Workgroup

2. Within 60 days of notice, HIE will convene a meeting of the Issue Remediation Workgroup
   - Members will be approved by Board
   - Workgroup may request information from TDSOs, but will not compel evidence

3. Within 15 days of workgroup meeting, the group will issue a nonbinding recommendation for the Board

4. The Board will have 60 days upon receiving the recommendation to issue a final decision

Emergency meetings can be called by the Executive Director of the HIE to prevent imminent, irrevocable harm

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Sharing Protected Health Information

- There are lots of reasons to share health data;
  - HIPAA describes what can be shared based on set of permitted purposes
  - HIPPA lays out a rule minimum data set

- To meet HIPAA requirements
  - Everything you want to share, is written into a new use case exhibit
  - Participants sign legal agreements based on that limited data set with the Health Information Network (HIN)

- There is no one size fits all
  - Instead, data sharing use cases start small and write use cases that define everything that we do

- In 5 years, when everyone is comfortable, it may be different

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HIPAA Organizing Principle

Covered entities* with relationships in common may share individually identifiable health information

✓The disclosure must pertain to the covered entity's relationship with the shared patient

✓Sharing must fall under one of the HIPAA permitted purposes of **treatment, payment, or healthcare operations** or as required by law

✓Sharing can occur for public health purposes*
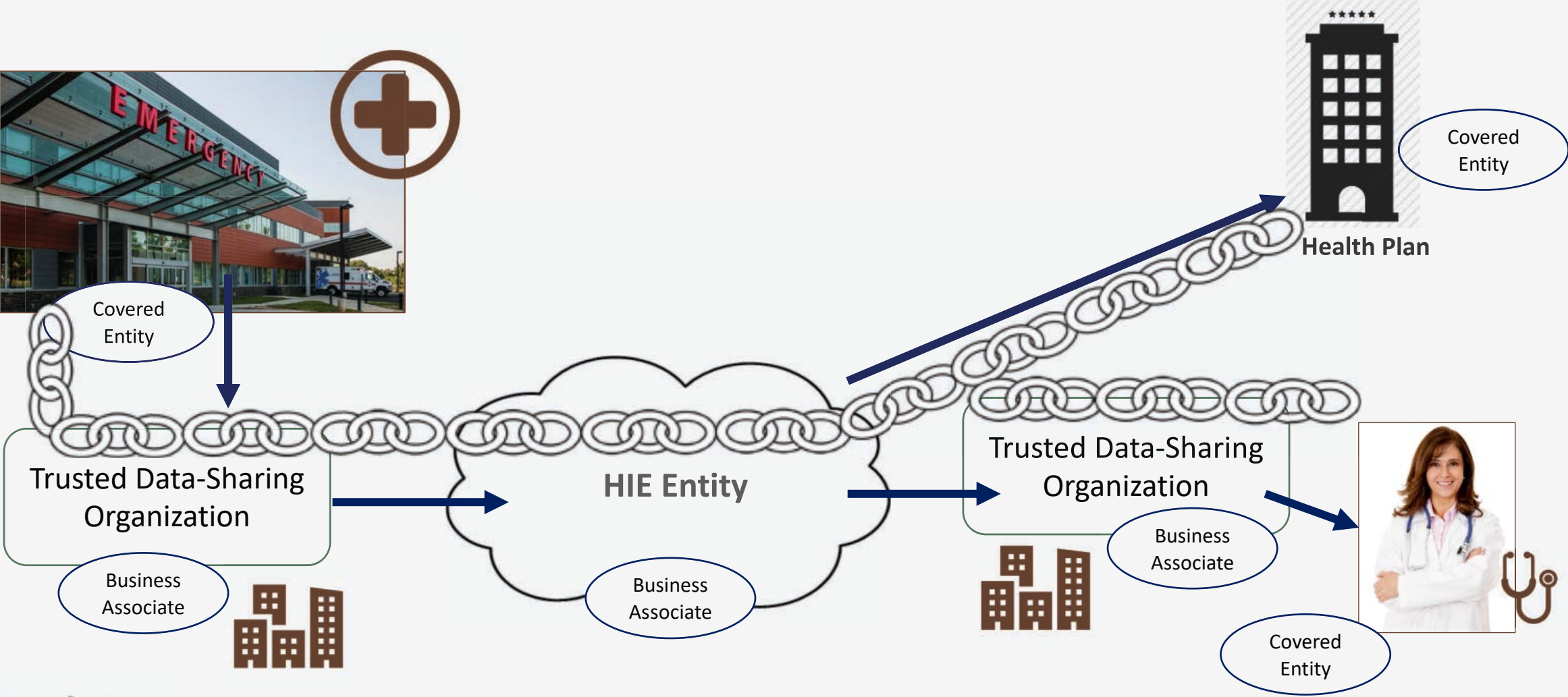
Organizing Principle for HIPAA Data Flows

> **Covered entities* with relationships in common may share individually identifiable health information**

- The disclosure must pertain to the covered entity's relationship with the shared patient

- Sharing must fall under one of the HIPAA permitted purposes of **treatment, payment, or healthcare operations** or as required by law

* Sharing can also occur for certain public health purposes

Note: See exception related to self-pay

HIPAA Chain of Trust

Covered Entity

Covered Entity

Health Plan

Trusted Data-Sharing Organization

Business Associate

HIE Entity

Business Associate

Trusted Data-Sharing Organization

Business Associate

Covered Entity

Next Session

- Discuss identity
- How we know people or organizations have patients in common
- Talk through some of the first few use cases envisioned
- Discuss the role of CDAS versus use cases

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Consent Policy Design Group – Workplan

Meeting Focus	Meeting Objectives
Meeting 1 – 4/9/2019 1pm – 2pm Kickoff and orientation	• Review and discuss project charter and proposed process for achieving desired outcomes • Orientation on relevant policies and procedures and semantic alignment / shared understanding of key terms
Meeting 2 – 4/23/2019 1pm – 2pm Current consent policies	• Establish understanding around current state of consent policies in Connecticut and bordering states • Consider draft language for a HIPAA TPO consent policy for recommendation to Advisory Council
Meeting 3 – 5/7/2019 1pm – 2pm Focus on TPO consent draft	• Review proposed process for the development of a consent policy framework, based on HIE use case requirements • Discuss stakeholder engagement and communication needs
Meeting 4 – 5/21/2019 1pm – 2pm Matching use cases to consent model	• Review and discuss received input from Advisory Council or other stakeholders • Review use cases where individual consent is required by state or federal law, or areas of ambiguity
Meeting 5 – 6/4/2019 1pm – 2pm Use Case A discussion	• Discuss the pros/cons of a statewide consent policy framework vs. HIE Entity consent policy framework to determine scope
Meeting 6 – 6/18/2019 1pm – 2pm Use Case B discussion	• Discuss the various ways that consent could be collected and possible roles for organizations in the consent process • Establish high-level understanding of technical architecture for electronic consent management solutions • Discuss workflows that could provide individuals with information and the ability to manage preferences
Meeting 7 – 7/9/2019 1pm – 2pm Review draft consent framework recommendations – structure and process	• Review and discuss strawman options • Develop draft recommendations for consent policy framework
Meeting 8 – 7/23/2019 1pm – 2pm Vote on draft recommendations	• Finalize and approve recommendations • Discuss stakeholder / general population engagement and communication process

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