Walgreens

Partnering for a more
connected healthcare ecosystem

Compliance Considerations for Decentralized Clinical Trials

Ethics, Equity, Technology, DCT Control Design

Selena Evans
Senior Director, Office of Ethics & Compliance, Walgreens

Adam Samson
Head of Clinical Delivery Operations, RWE Clinical Trials, Walgreens

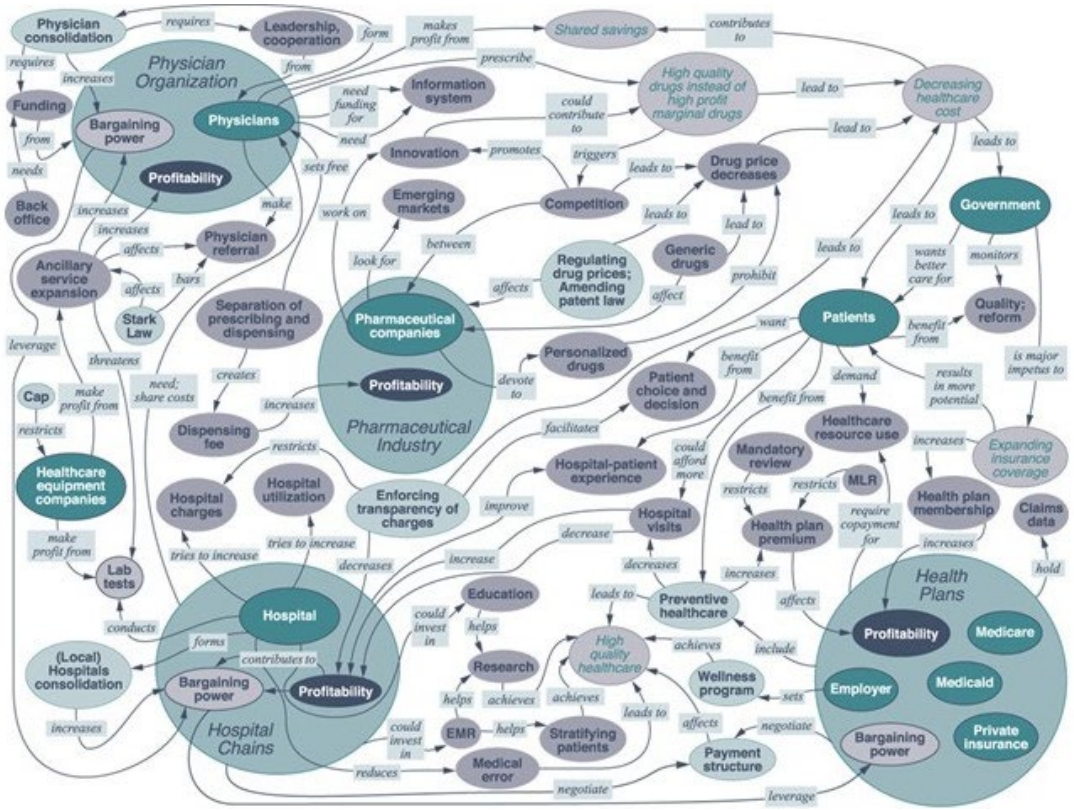
Clinical Trials Ecosystem

Ecology, Ethics & Compliance

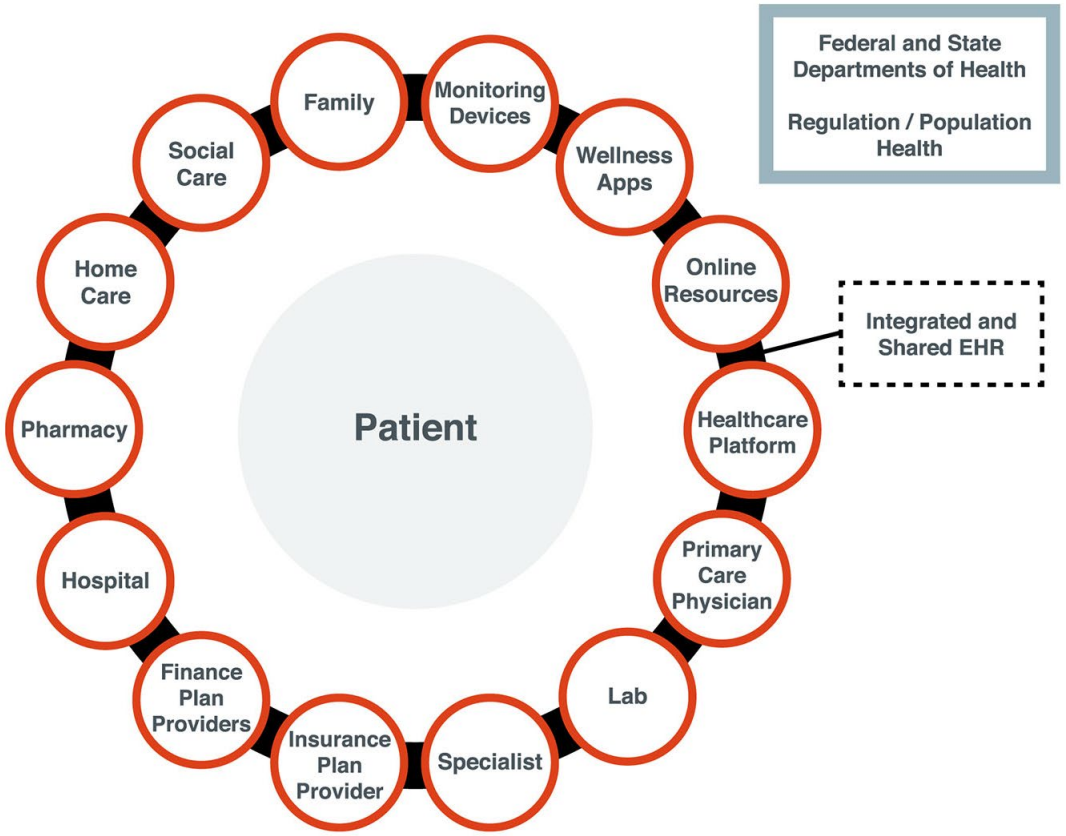
> “ Business ecology is based on the elegant structure and principles of natural systems. It recognizes that to develop healthy business ecosystems, leaders and their organizations must see themselves, and their environments, through an ‘ecological lens’.

Abe, Joseph M.; Dempsey, Patricia E.; Bassett, David A. (1998). Business Ecology: Giving Your Organization the Natural Edge. Boston: Butterworth-Heinemann.

Healthy Healthcare Ecosystem



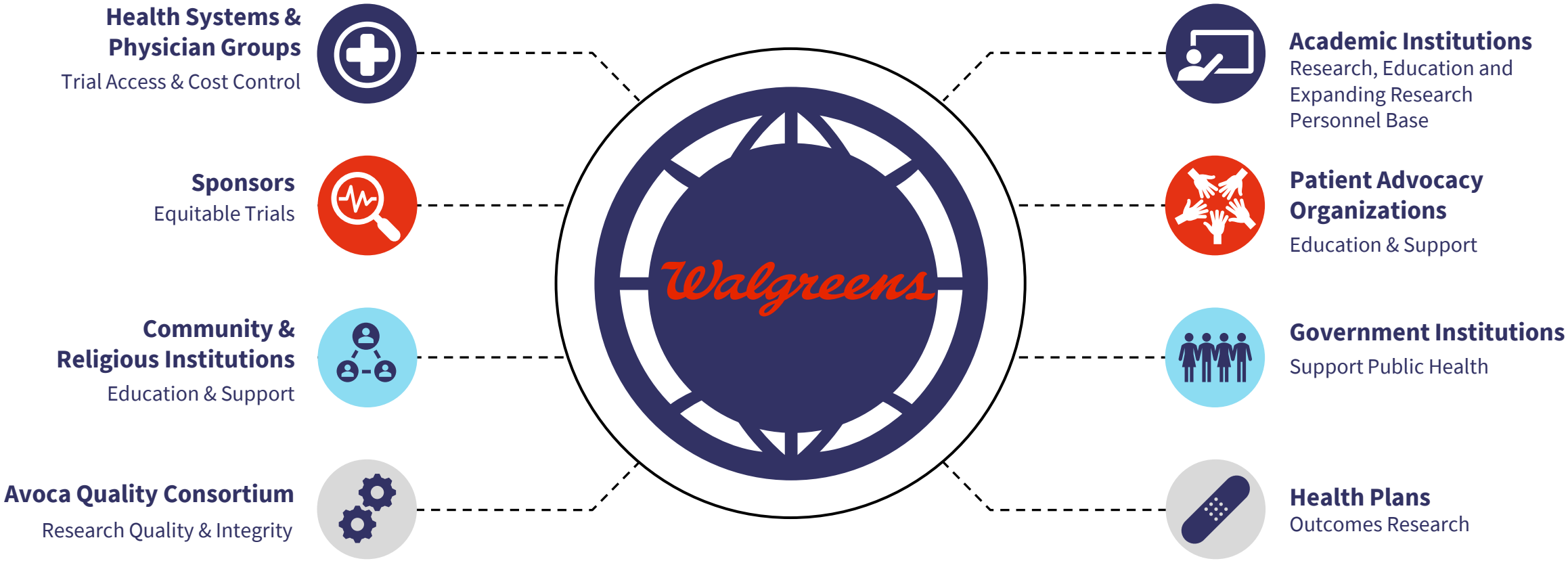
Robert Lawton Burns. 2022. The U.S. Healthcare Ecosystem: Payers, Providers, Producers, Health Management, Policy and Innovation (www.HMPI.org), V7-1



Navigating the Healthcare Ecosystem (endava.com)

Community Based Trials Are the Future

Walgreens Clinical Trial Ecosystem Is A Powerful Solution



Clinical Research Ecosystem Transformation

Digital ◆ Physical ◆ Philosophical

Digital Optimization to Advance Community-based Research

- Community Partnering
- SDOH-informed decision pathways
- Digital Health Equity
- Community Gap Analysis/ Needs Assessment
- Patient-centered, UX design approach
- Cultural and linguistically appropriate Clinical Trial Education

The Walgreens Digital Clinical Trial Participant

Integrating research and clinical care with access to digital information presents enormous potential to benefit the research enterprise and health outcomes.

Robert M. Califf, M.D., *Commissioner U.S. Food and Drug Administration*

Translational Science

Decentralized Clinical Trials for Drugs, Biological Products, and Devices

Guidance for Industry, Investigators, and Other Stakeholders

DRAFT GUIDANCE

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Oncology Center of Excellence (OCE)

May 2023
Clinical/Medical

Governance Model for Research Integrity

Senior Leadership Team

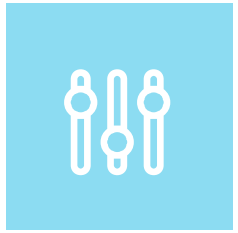
Customer Portfolio Committee	*Operations Committee*	*Patient Integrity Committee*	*External Partnerships Committee*	*Compliance & Privacy Steering Committee*
	Quality *Standards* *Regulatory Change Management*			

Patient Integrity Program, Safety, Informed Consent & Engagement

Our Patient Integrity Program maintains, measures and verifies our commitments to patient empowerment and safety, from providing fulsome information to ensuring ethical analytics and culturally appropriate engagement to deliver a compliant and trustworthy patient experience.

Protocol Compliance & Quality Assurance

Protocol requirements are carefully overseen, documented and audited for completeness and accuracy to ensure patient safety and preserve clinical integrity in accordance with the FDA's GCP regulations and guidance.



Trial Site & Investigational Products

Trial sites are prepared and audited to ensure adherence to protocol and comfort for participants. If applicable, shipment, storage, handling, and administration of investigational products are carefully documented and tracked.

Data Privacy, Security, Quality & Integrity

Data is rigorously protected to maintain privacy, ensure accurate documentation, reporting and adherence to regulations, including HIPAA and 21 C.F.R. Part 11.

Compliant Infrastructure

Internal operations must compliantly support all CT activities, including strategic partnership management, billing practices, program architecture, roles & responsibilities segregation, data & information flows, internal training programs and governance.

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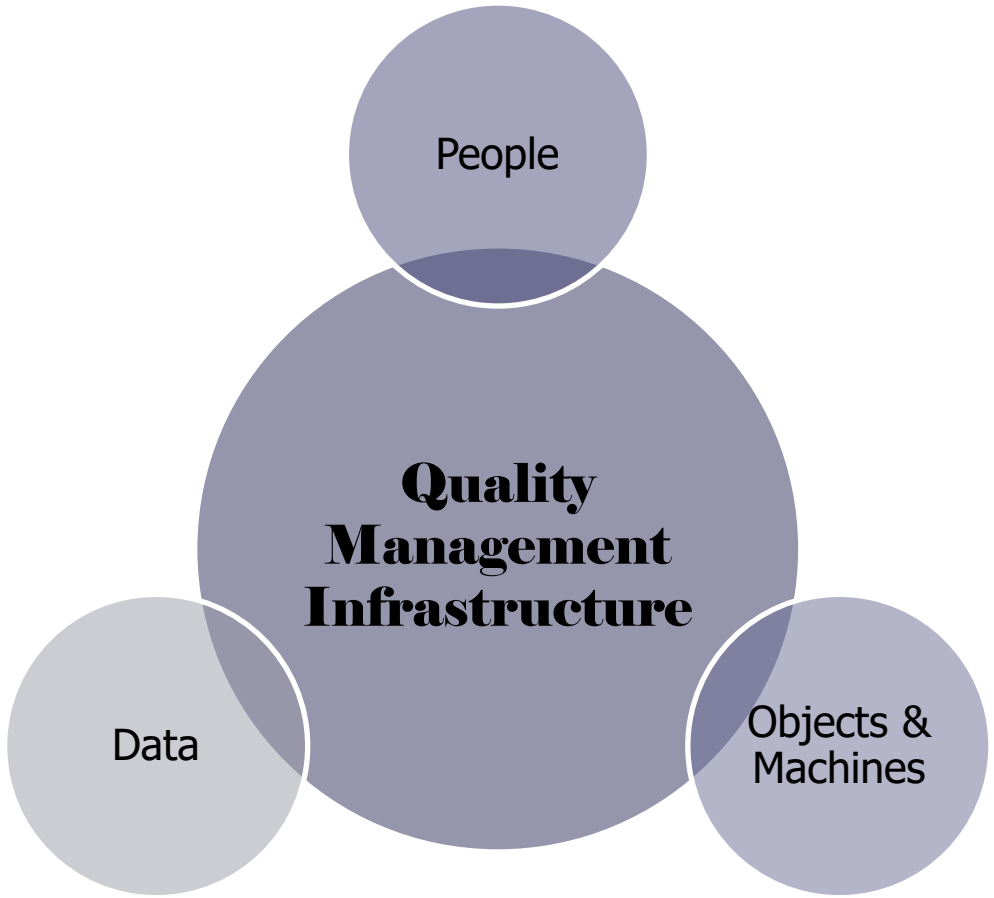
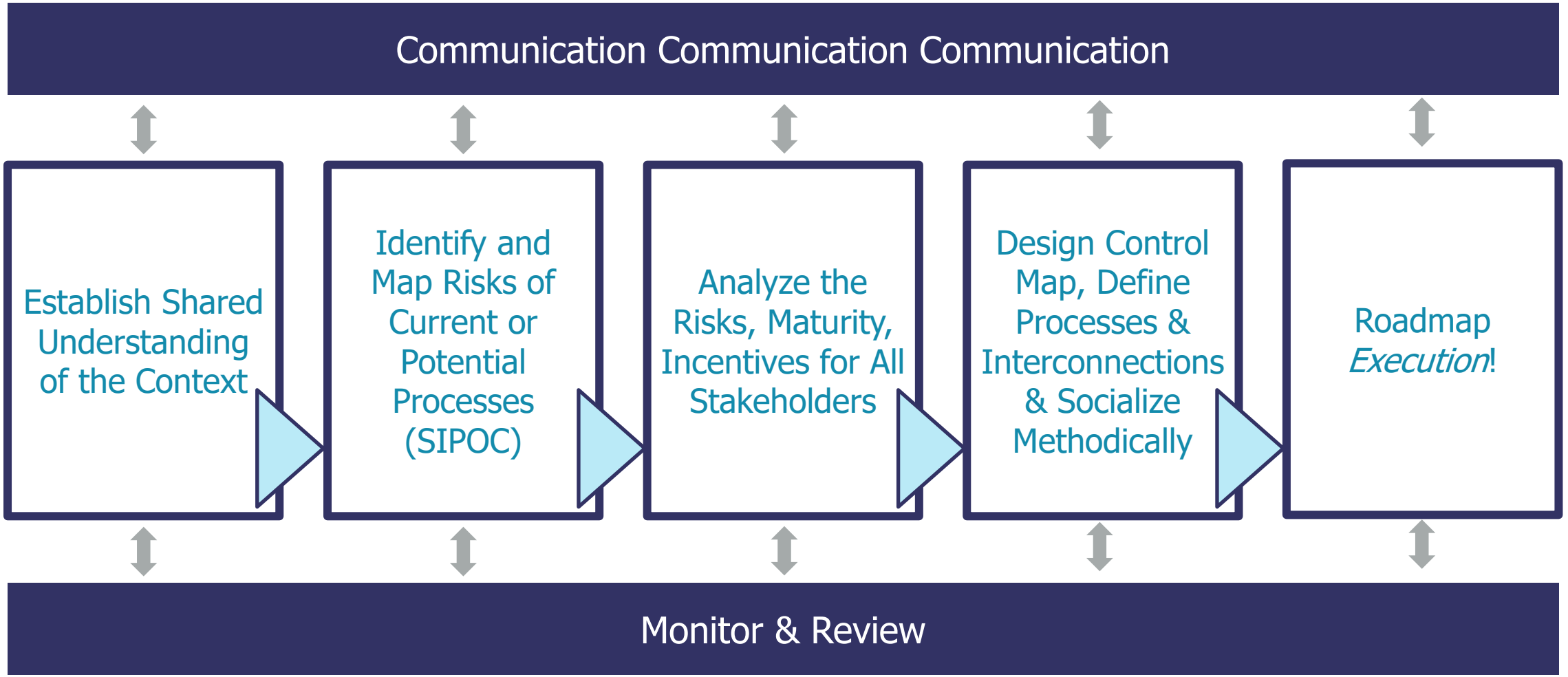
Ecosystem Control Design | Managing Interconnections



- Value Stream Mapping
  - Creation
  - Delivery
  - Capture
- Enterprise Architecture
- Communication Flows
- Data Lifecycle Management
- Maturity Modeling
- Continuous Improvement & Sustainability
- **Voice of the Customer & Equity**

Radziwill, N.M., *Connected, Intelligent, Automated: The Definitive Guide to Digital Transformation and Quality 4.0*

Ecosystem Control Design



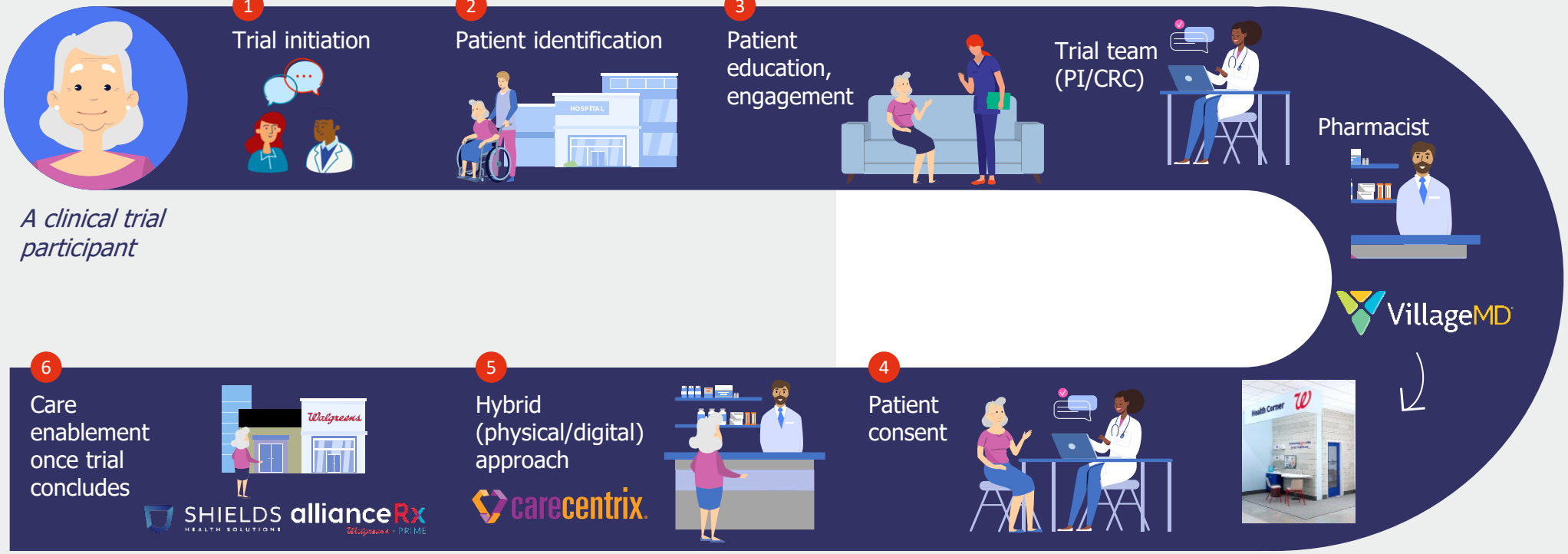
Compliance & Quality Management for Ecosystem Health

Harmonizing people, processes and technologies to deliver results.

- Systems thinking
- Data-informed decision making
- Leadership for organizational learning
- Defining processes & managing continuous improvement
- Capture consequences

Radziwill, N.M., *Connected, Intelligent, Automated: The Definitive Guide to Digital Transformation and Quality 4.0*

Flexible Operating Model to Support Individualized Journeys



VillageMD
Summit Health
Primary Care

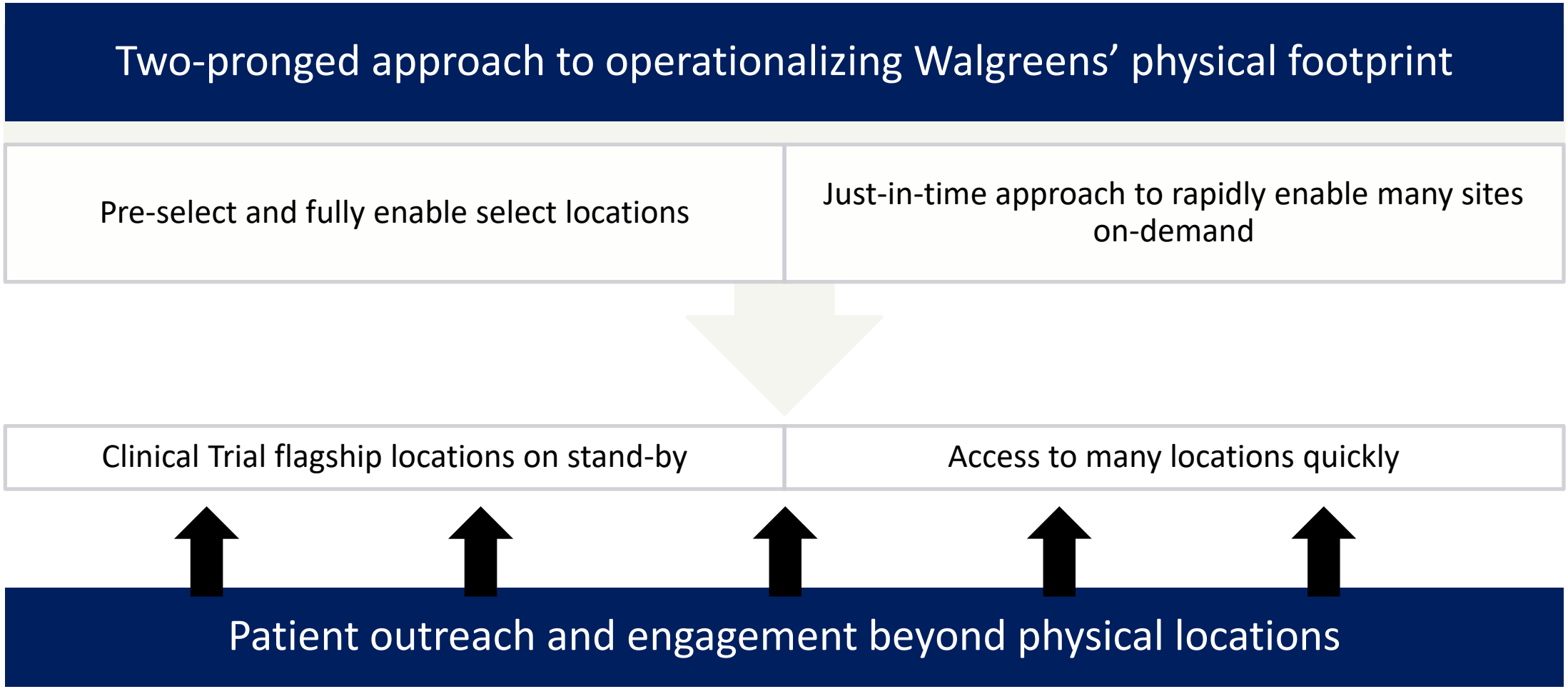
carecentrix
Post Acute / Home Health

allianceRx Walgreens PRIME
Specialty Pharmacy
Oncology Care Management

SHIELDS HEALTH SOLUTIONS
Specialty Pharmacy
Collaborative Care

Quality by design ensures integrity of research offerings from both patient and regulatory perspectives.

Our Approach to Decentralized Clinical Trial Delivery



Walgreens Boots Alliance

Site-Based Capabilities

Across our site network, we're able to facilitate community-based clinical trial conduct.

Our sites and our staff are matched to the needs of community-based trial visits and are able to support trial conduct across a broad array of therapeutic areas.

Prescreening	Consenting	Eligibility Assessment	Vital Signs
Anthropometrics	Phlebotomy	Electrocardiogram	POC Diagnostics
Medical History	Medication Review	Clinical Outcome Assessments	Safety Event Reporting

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Thank you!