Maintaining Research Integrity in a Changing Environment

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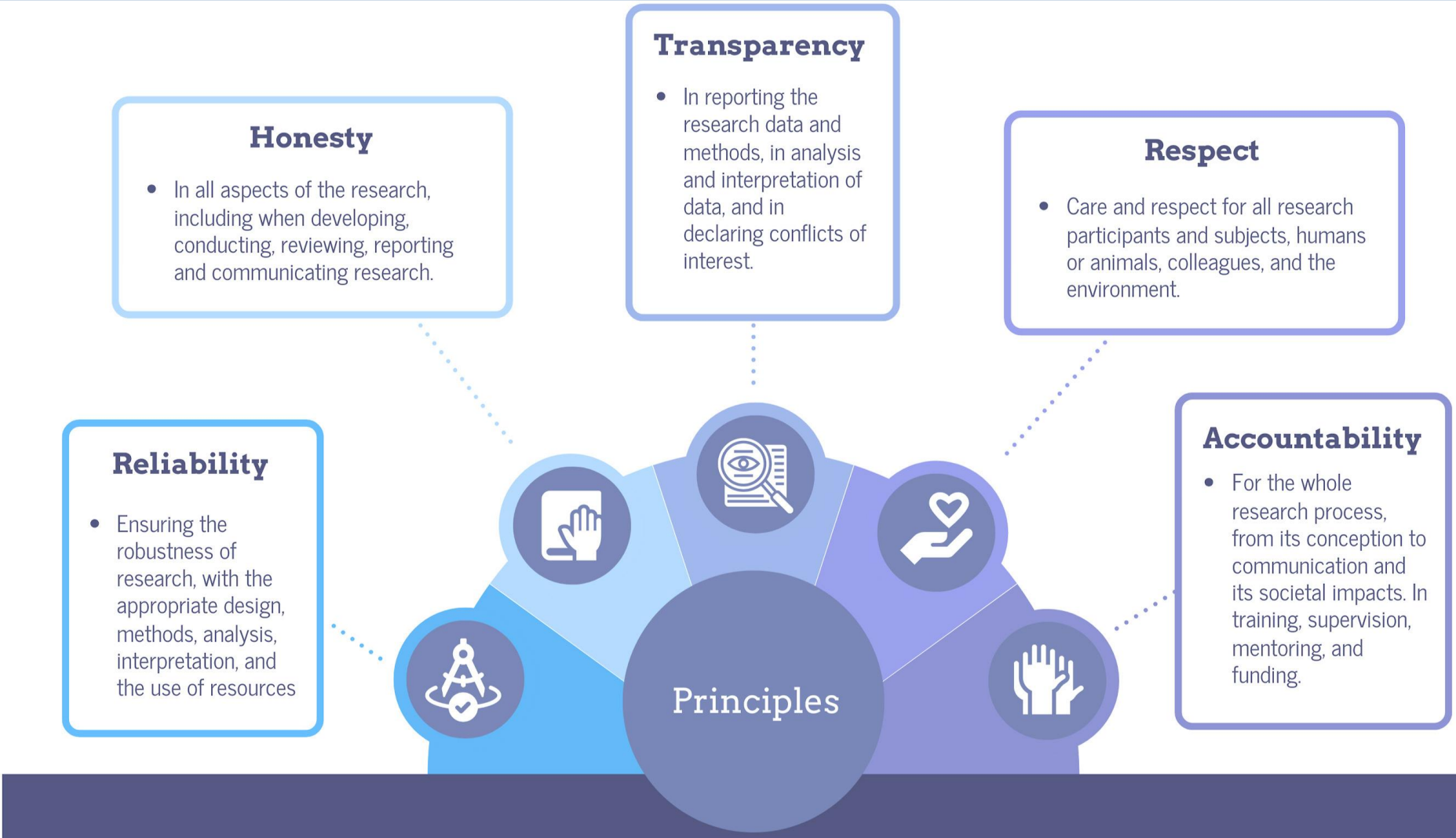
Agenda

- What is research integrity?
- Where we are now?
- Where do we want to go?
- How do we navigate this transition?



Research Integrity

- Armond, Cobey, Moher. Key concepts in clinical epidemiology: research integrity definitions and challenges. J Clin Epidemiol, 171 (2024), Article 111367
- https://ori.hhs.gov/

Clinical Ethics

The 4 principles of ethics:

- Beneficence
- Nonmaleficence
- Autonomy
- Justice

Varkey B. Principles of Clinical Ethics and Their Application to Practice. Med Princ Pract. 2021;30(1):17-28.

NIH Clinical Center researchers published seven main principles to guide the conduct of ethical research:

- Social and clinical value
- Scientific validity
- Fair subject selection
- Favorable risk-benefit ratio
- Independent review
- Informed consent
- Respect for potential and enrolled subjects

https://www.nih.gov/health-information/nih-clinical-research-trials-you/guiding-principles-ethical-research

Carilion Clinic Vision 2025

Vision Statement

We provide world-class health care through integrated clinical practice, education and ***patient-centered research***. We develop and respect an experienced, talented workforce. We serve for the love of health.

Our Commitment:

Navigating the challenges and opportunities that come with expanding research programs while upholding rigorous scientific and ethical standards

Research at Carilion Clinic is growing at an unprecedented pace

- In 2024, over 200 Carilion physicians collaborated on more than 140 clinical trials across 20+ medical and surgical specialties
- $2.7 million in new trial awards and $14 million in new grant funding
- In March 2025, Carilion IRB had 440 active protocols.

Research at Carilion Clinic is growing at an unprecedented pace

With this remarkable momentum, Carilion is committed to ensuring that research continues to thrive with structure, strategy, and impact

Where are we now?

- Research and Development: Research and Development | Carilion Clinic
- Human Research Protection Office (IRB's and more):Institutional Review Board (IRB) | Carilion Clinic
- Health Analytics Research Team (HART):Health Analytics Research Team | Carilion Clinic
- Research Opt-Out Process: New Consent to Treatment form-- General Consent to Treatment and Financial Agreement | Carilion Clinic
  - **Contact patients about research participation**. We conduct many research studies to learn about new treatments and ways to prevent health problems. Patients may be invited to participate. Patients who do not want to be contacted about research can opt out by calling 540-224-6744 or emailing **optoutresearch@carilionclinic.org**.

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Clinical Trials

Research and Clinical Trials at Carilion

Carilion Clinic conducts clinical trials in three main areas—investigational drugs, biologics and devices—across 18 clinical areas ranging from cancer and cardiovascular studies to pediatrics and surgical techniques.

Cancer	Endovascular Surgery	Neurosurgery	Rheumatology
Cardiology	Family Medicine	Orthopaedics	Surgery
Dermatology	Gastroenterology	Pediatrics	Urology
Emergency Medicine	Infectious Diseases	Psychiatry and Psychology	
Endocrinology	Inpatient Research	Pulmonology	

What Is a Clinical Research Trial?

Investigational products, devices and procedures go through several stages of testing to demonstrate their safety and effectiveness before they can be approved by the U.S. Food and Drug Administration for widespread use and marketing. The video below from the National Institutes of Health illustrates the general process.

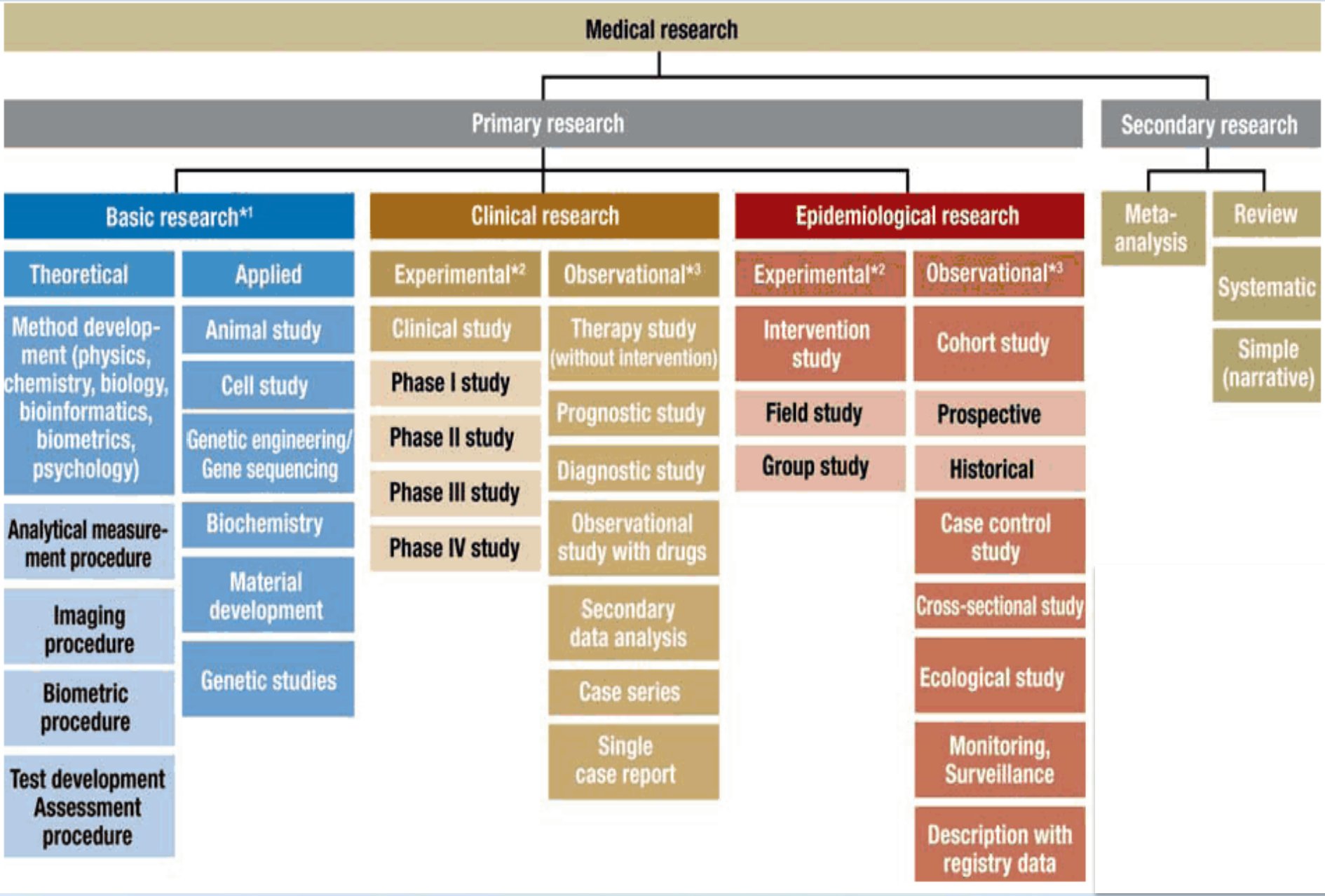
At Carilion, each clinical trial has a lead study physician, known as the Principal Investigator, and dedicated clinical research support staff who can help potential participants find out if they're eligible, get enrolled and navigate their participation.

Clinical trials for investigational drugs and products are categorized in the following phases:

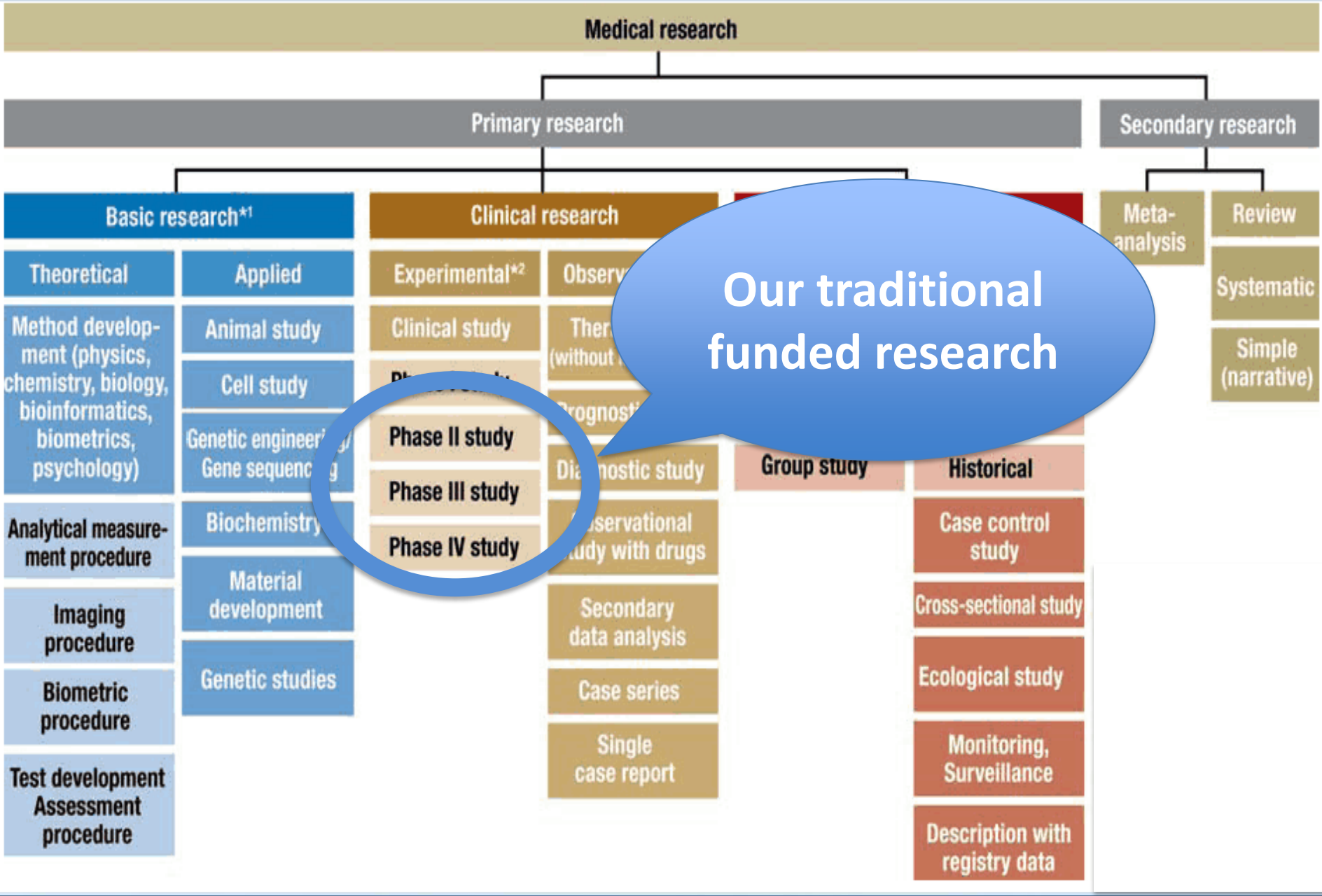
Phase I

Phase I of a clinical trial typically involves a small number of participants who are healthy control participants. Phase I trials are the first in humans, and they determine whether the product is safe for use.

Where do we want to go?

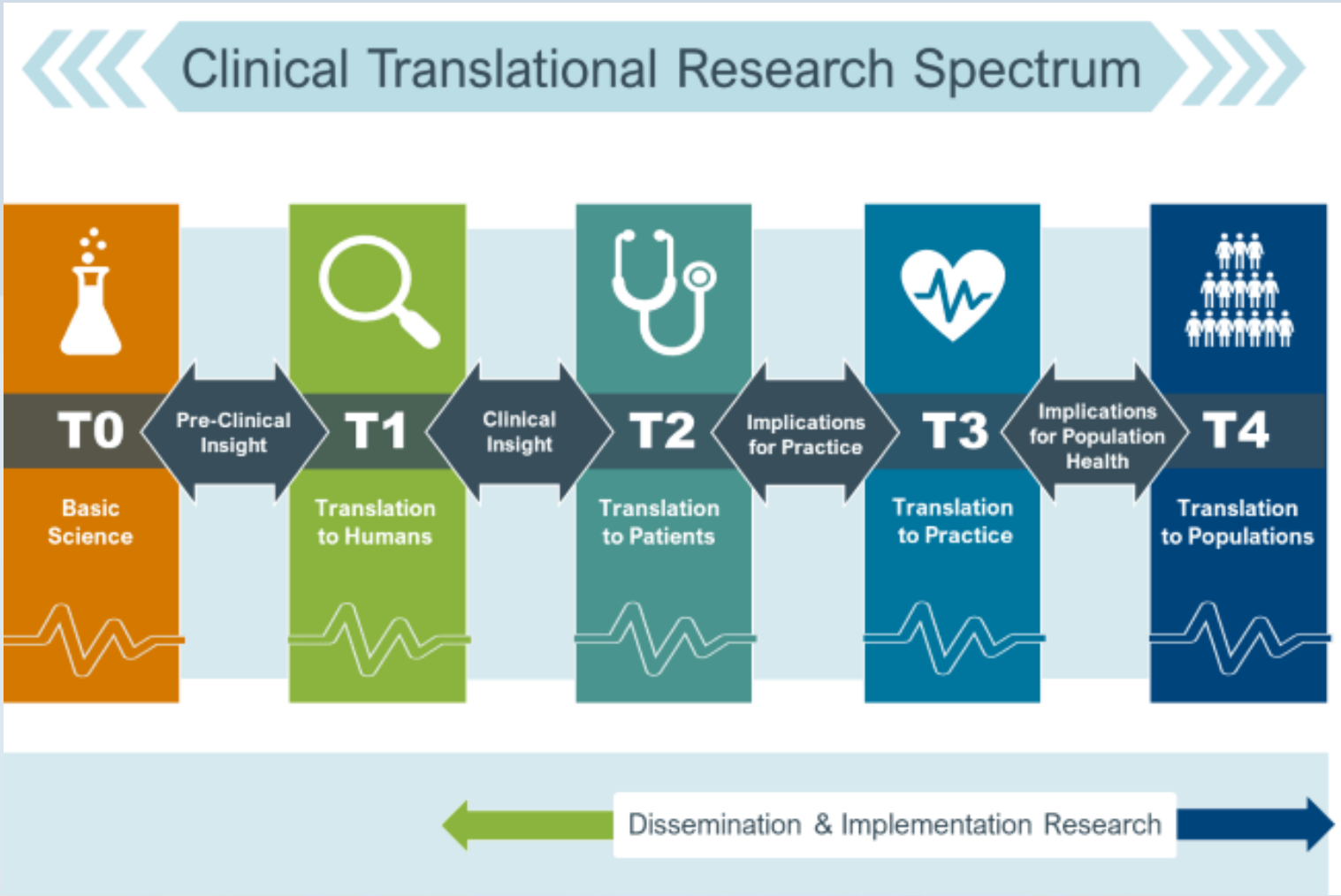


Dtsch Arztebl Int 2009; 106(15): 262-8. DOI: 10.3238/arztebl.2009.0262



Dtsch Arztebl Int 2009; 106(15): 262-8. DOI: 10.3238/arztebl.2009.0262

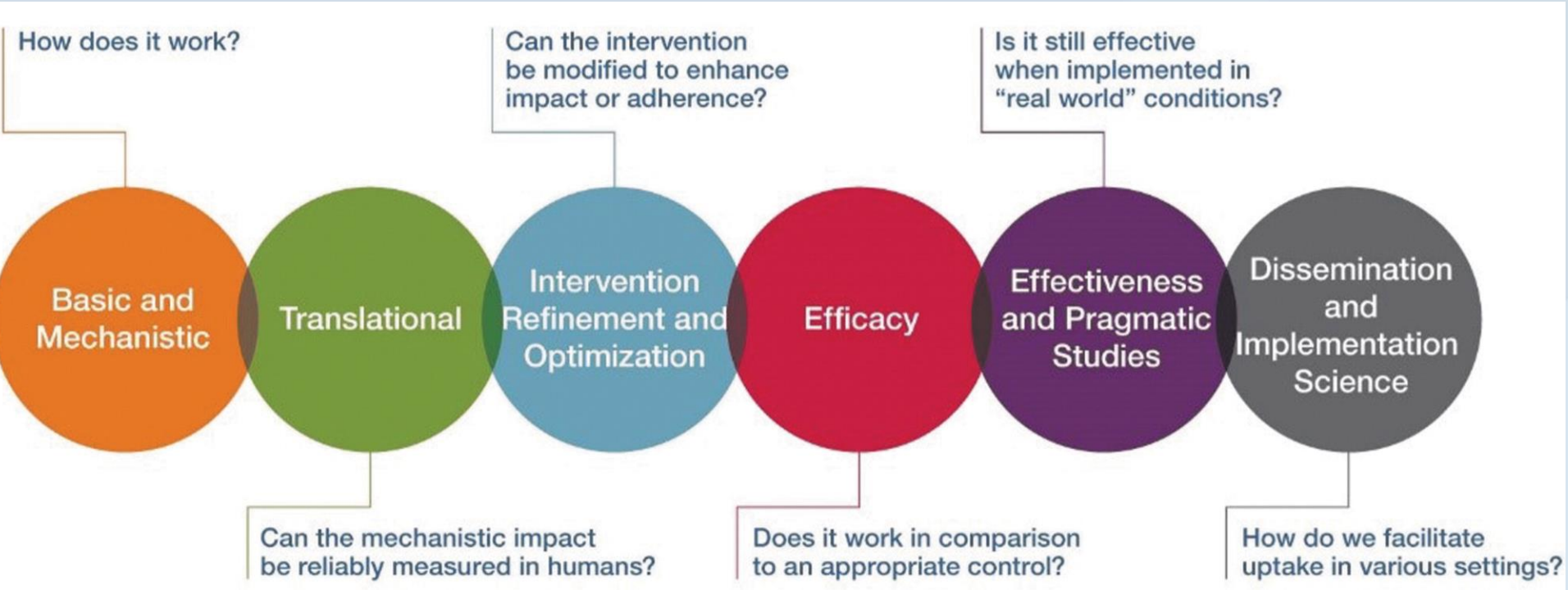
Carilion's Vision is Patient-Centered Research



https://research.musc.edu/resources/sctr/programs/disc

Carilion's Future Research Focus?

Improving the outcomes of patient care



https://www.liebertpub.com/doi/10.1089/acm.2020.0446

How do we navigate this transition?

Research Governance Council

- **Charge**:
  - To oversee and coordinate Carilion Clinic's research enterprise in collaboration with our key research partners and the community
- **Committees:**
  - Education & Faculty Development
  - Innovation & Commercialization
  - Health Systems & Implementation Science
  - Operations and Finance
  - Data Sharing Technology & Informatics
  - Compliance Oversight

Present Research Partners

VTC
Virginia Tech Carilion
School of Medicine

Department of Health Systems and Implementation Science

and many drug and device companies

- Expanding research programs in a large healthcare system presents both challenges and opportunities.

- First: Consider carefully the impact on the participant who is also a patient. We have a primary ethical obligation to do no harm.

Challenges

1. Funding Instability:

- Issue: Fluctuations in funding, including freezes on federal grants and cuts to indirect cost rates, can disrupt research programs
- Solution: Diversify funding sources by seeking grants from multiple agencies, private foundations, and industry partnerships. Establishing endowments can also provide more stable financial support.

2. Regulatory Compliance:

- Issue: Navigating complex regulations and ensuring compliance with ethical standards can be daunting
- Solution: Develop a robust compliance framework and invest in training for staff on regulatory requirements. Utilize software tools to streamline compliance monitoring and reporting.

3. Ethical Standards:

- Issue: Ensuring ethical conduct in research, particularly involving human subjects, is critical
- Solution: Establish ethics committees to review research proposals and ensure adherence to guidelines such as the Declaration of Helsinki and the Belmont Report
- Regularly update training programs on ethical standards for researchers.

4. Data Management:

- Issue: Handling large volumes of data securely and efficiently can be challenging
- Solution: Implement advanced data management systems and protocols to ensure data integrity and security. Invest in cybersecurity measures to protect sensitive information.

5. Interdisciplinary Collaboration:

- **Issue**: Facilitating collaboration across different departments and specialties can be difficult
- **Solution**: Create interdisciplinary research teams and foster a culture of collaboration through regular meetings and shared goals. Utilize collaborative platforms and tools to enhance communication.

Opportunities

1. Technological Advancements:

- Opportunity: Leveraging new technologies can enhance research capabilities
- Solution: Invest in cutting-edge technologies such as genomic profiling, precision imaging, and AI-driven data analysis to accelerate research and improve outcomes.

2. Patient-Centered Research:

- Opportunity: Focusing on patient-centered outcomes can improve care and drive innovation
- Solution: Engage patients and communities in the research process to ensure studies address real-world needs. Use patient feedback to refine research questions and methodologies.

3. Scalable Solutions:

- Opportunity: Developing scalable solutions can extend the impact of research
- Solution: Design research programs that can be easily scaled and adapted to different settings. Focus on creating platforms and tools that can be widely implemented.

4. Health Equity:

- Opportunity: Addressing health disparities can lead to more inclusive and impactful research
- Solution: Prioritize research that targets underserved populations and aims to reduce health disparities. Collaborate with community organizations to ensure equitable access to research opportunities.

Carilion Research

Improving Care, Driving Innovation

References

Caught in the crossfire: The critical threats facing cancer centers, research, and patient care Caught in the crossfire: The critical threats facing cancer centers, research, and patient care - The Cancer Letter

Ensuring ethical standards and procedures for research with human beings Ensuring ethical standards and procedures for research with human beings

Guiding Principles for Ethical Research Guiding Principles for Ethical Research | National Institutes of Health (NIH)

Ethical Codes & Research Standards Ethical Codes & Research Standards | HHS.gov

Health Policy Challenges for 2025 and Beyond Health Policy Challenges for 2025 and Beyond | JAMA Forum | JAMA Health Forum | JAMA Network