

# Introduction to Clinical and Translational Research at UMB

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This course is jointly sponsored by the University of Maryland School of Medicine Department of Epidemiology and Public Health, the University of Maryland Claude D. Pepper Older Americans Independence Center (UM-OAIC) and the Baltimore VA Medical Center, Geriatric Research Education and Clinical Centers (GRECC).



# NIH Roadmap

“It is the responsibility of those of us involved in today’s biomedical research enterprise to translate the remarkable scientific innovations we are witnessing into health gains for the nation”

Elias Zerhouni, MD  
Former Director, National Institutes of Health  
NEJM 2005

# Four Phases of Translational Research

- Phase 1 translation (T1) research seeks to move a basic discovery into a candidate health application.
- Phase 2 translation (T2) research assesses the value of T1 application for health practice leading to the development of evidence-based guidelines.
- Phase 3 translation (T3) research attempts to move evidence-based guidelines into health practice, through delivery, dissemination, and diffusion research.
- Phase 4 translation (T4) research seeks to evaluate the "real world" health outcomes of a T1 application in practice.

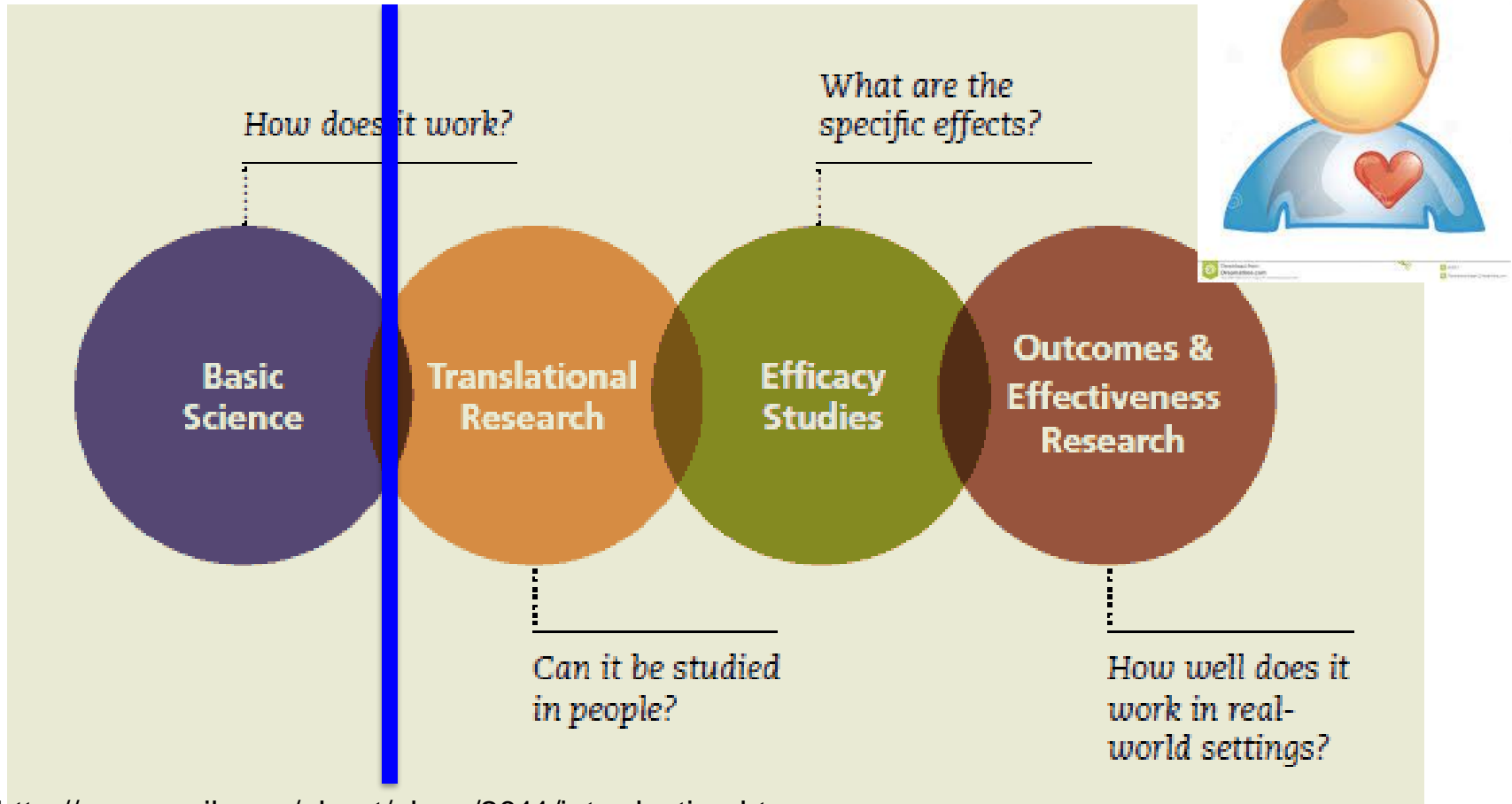
# Pentavalent Rotavirus Vaccine Development as an Example of Pediatric Translational Research.

Research nomenclature				
Selected studies	Design	Clinical trial phase	IOM translational definition	Expanded translational definition
[28, 29]	Product discovery	Basic science, preclinical	T1	T1
[14, 30]	Safety	I	T1	T1
[14, 30]	Immunogenicity	II	T1	T1
[14, 30]	Efficacy	III	T2	T2
[6, 23, 24, 26, 27]	Effectiveness	IV	T2	T3
[4, 31–35]	Disease burden, population outcome, policy impact, cost-benefit, cost-effectiveness	...	T2	T4

**NOTE.** IOM, Institute of Medicine.

Geoffrey A. Weinberg, and Peter G. Szilagyi *J Infect Dis.*  
2010;201:1607-1610

# What is Clinical and Translational Research?



# Course Objectives

- Identify a research question
- Pick a study design
- Collect and manage data
- Analyze data
- Scientific Communication
  - Write an abstract
  - Present a poster
  - Give an oral presentation
  - Publish a paper
  - Prepare a grant
- Identify institutional resources
- Appreciate the ethical, legal and regulatory issues in human subjects research
- Understand the multidisciplinary nature of research
- Recognize career opportunities in clinical and translational research

# Suggested (but not required) Textbook

- Designing Clinical Research.
  - 4th Edition.
  - Stephen B. Hulley, Steven R. Cummings, Warren S. Browner, Deborah G. Grady and Thomas B. Newman.
  - ~\$40-60

# Important Websites

- Clinical Research Training and Education Program  
<http://www.medschool.umaryland.edu/k30/>
- Office of Research Career Development  
<http://www.medschool.umaryland.edu/career/>
- General Clinical Research Center  
<http://www.medschool.umaryland.edu/GCRC/>
- Human Research Protections Office  
<http://www.umaryland.edu/hrp/>
- Office of Research and Development  
<http://www.umaryland.edu/ord/>



# Other “Handouts”

- UMB Institutes, Centers and Programs
- PCOR/CER Training Opportunities

# Other Important Details

- Log in daily if you want a Certificate of Attendance
- Your house/office food and drink rules apply
- I have no idea where your restroom is located
- Be on time for and be engaged during presentations
- Fill out on-line evaluations

# Webex Housekeeping Tips



- Keep yourself **muted** unless instructed otherwise



- To ask a question, type it in the chat box and send to “**everyone**” not just the host
- If you prefer to ask a question verbally, type “**I have a question**” in the chat box and moderator will call on you at an appropriate time
- If you lose audio/video capabilities, logout of Webex and log back in

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Questions?

