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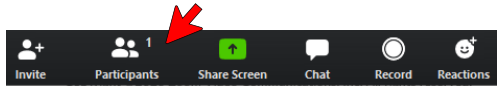
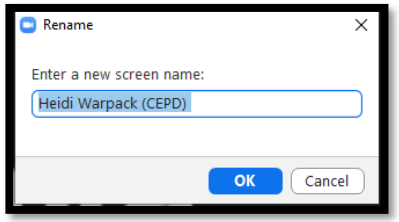
Thank you for joining us
Research Webinar will begin shortly

In the meantime, please rename yourself with your FIRST name LAST name (unit/department)

1. Click on “Participants” in banner at the bottom 

2. Find you name/SID/phone number and hover over it, click “More >”
3. Click “Rename” 

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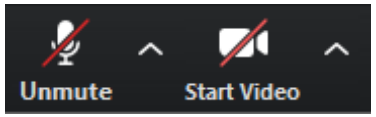
- Make sure you mute yourself if you are not speaking
  - You can view this in your bottom left banner



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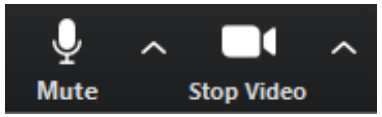

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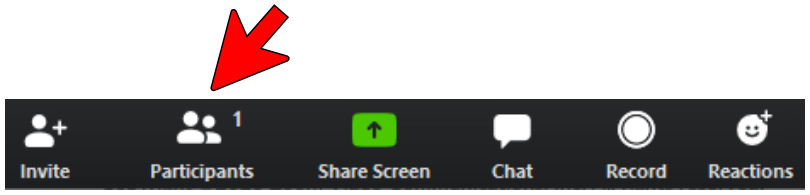
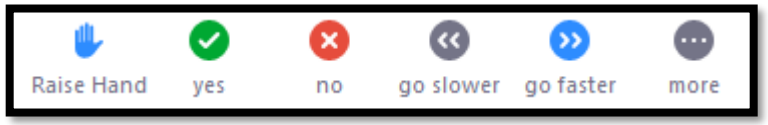
- You will be asked to participate throughout the workshop, please raise your hand before you speak to avoid multiple people speaking at once





The Role of Bedside Nurses in Clinical Trials

Presented by: Nick Berte, MSN, RN
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Objectives

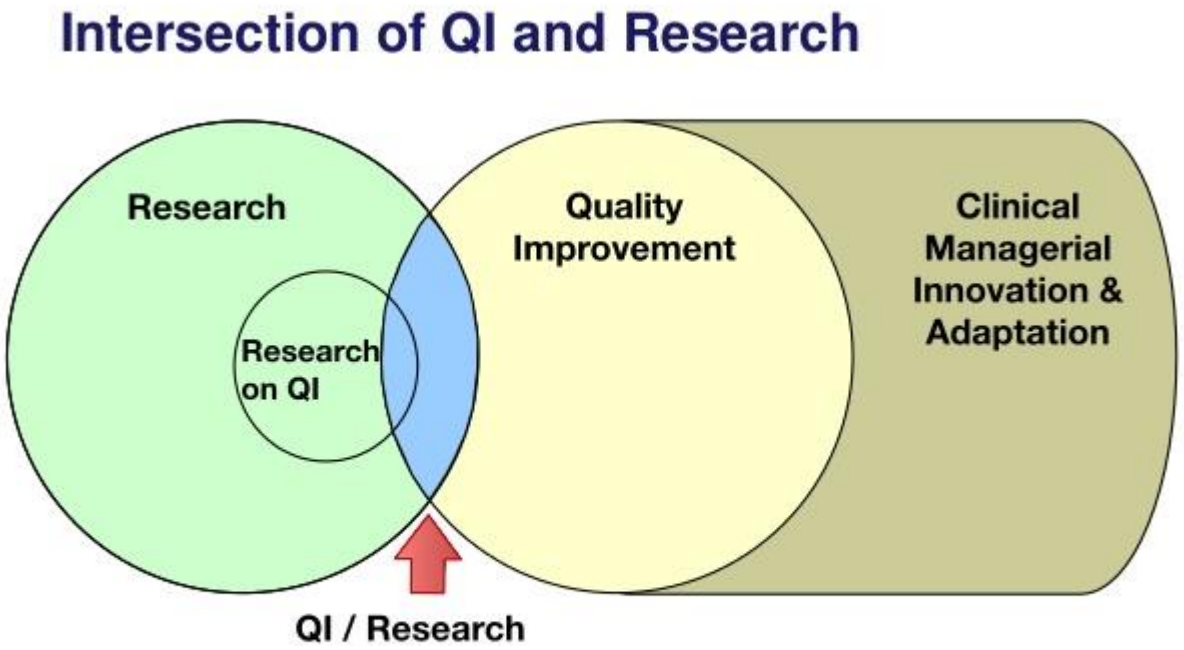
- Describe the differences between clinical trials, evidence based practice, and quality improvement projects.
- Verbalize common types of clinical trials. Drugs, Devices, Procedures.
- Discuss the various phases of clinical drug trials.
- Recognize how the nurses role is fundamental to study fidelity.
- Identify bedside RN contributions to science through clinical trials work.

Survey Questions

- Q: Do you currently have clinical trials on your unit?

- Q: Have you ever participated in a clinical trial as a bedside provider?

QI & Research



Adapted from: Hastings Center Report, July - Aug 2006

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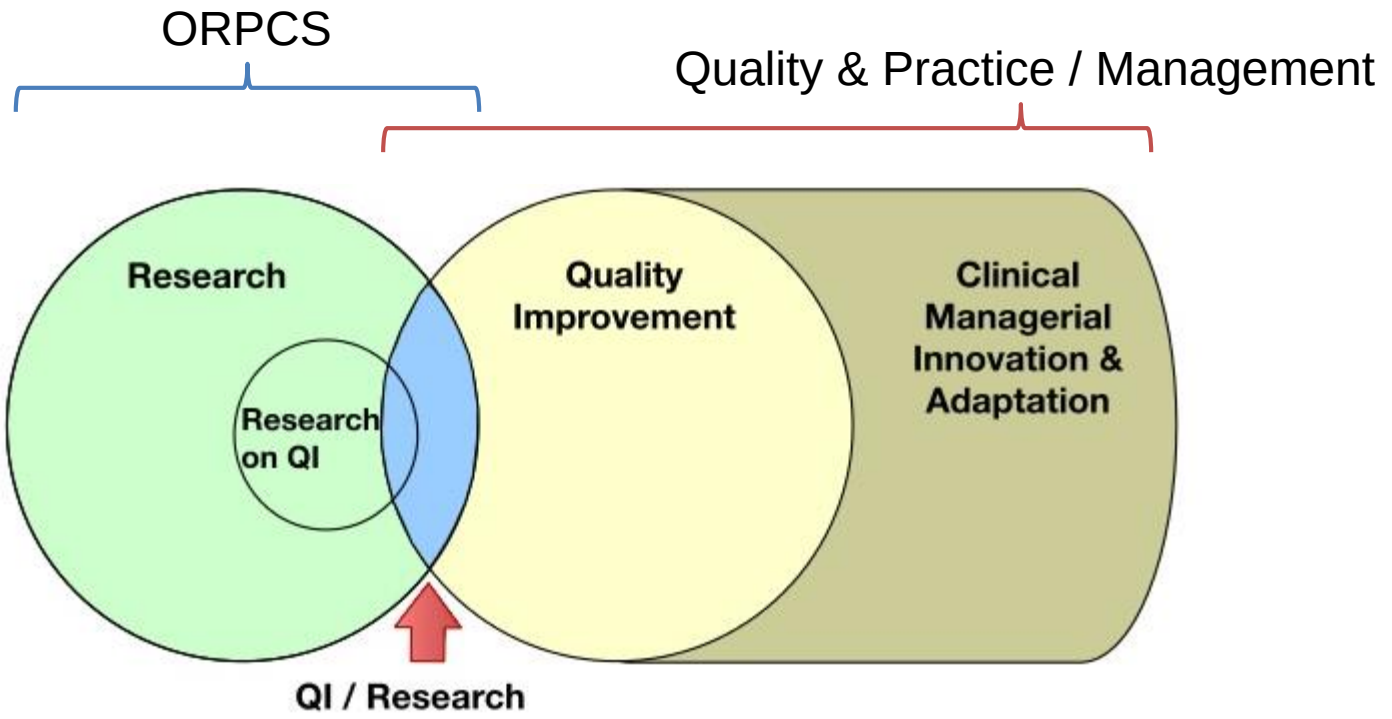
QI & Research

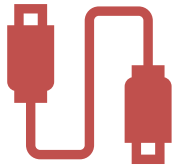

ORPCS
Quality & Practice / Management
Research
Research on QI
Quality Improvement
Clinical Managerial Innovation & Adaptation
QI / Research

QI vs Research

Points to consider	Research	QA/QI
Purpose	To test a hypothesis OR establish clinical practice standards where none are accepted	To assess or promptly improve a process, program, or system; OR improve performance as judged by accepted/established standards
Starting Point	To answer a question or test a hypothesis	To improve performance
Benefits	Designed to contribute to generalizable knowledge and may or may not benefit subjects	Designed to promptly benefit a process, program, or system and may or may not benefit patients
Risks/ Burdens	May place subjects at risk and stated as such	By design, does not increase patient's risk, with exception of possible privacy/confidentiality concerns
Data Collection	Systematic data collection	Systematic data collection
End Point	Answer a research question	Promptly improve a program/process/system
Testing/ Analysis	Statistically prove or disprove a hypothesis	Compare a program/process/system to an established set of standards.

Types of Clinical Trials

Drugs



Devices

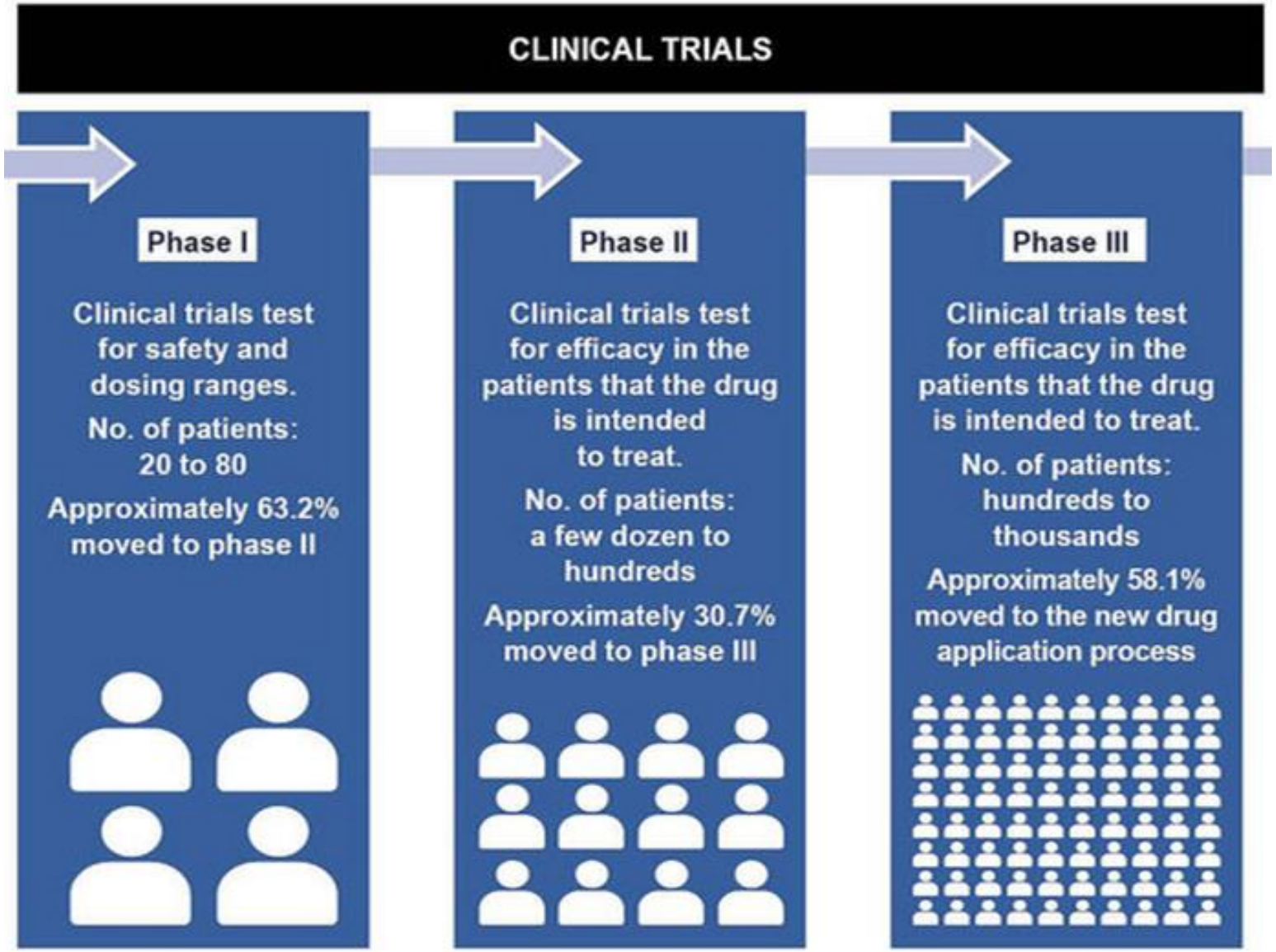
Procedures

Changes to Behavior

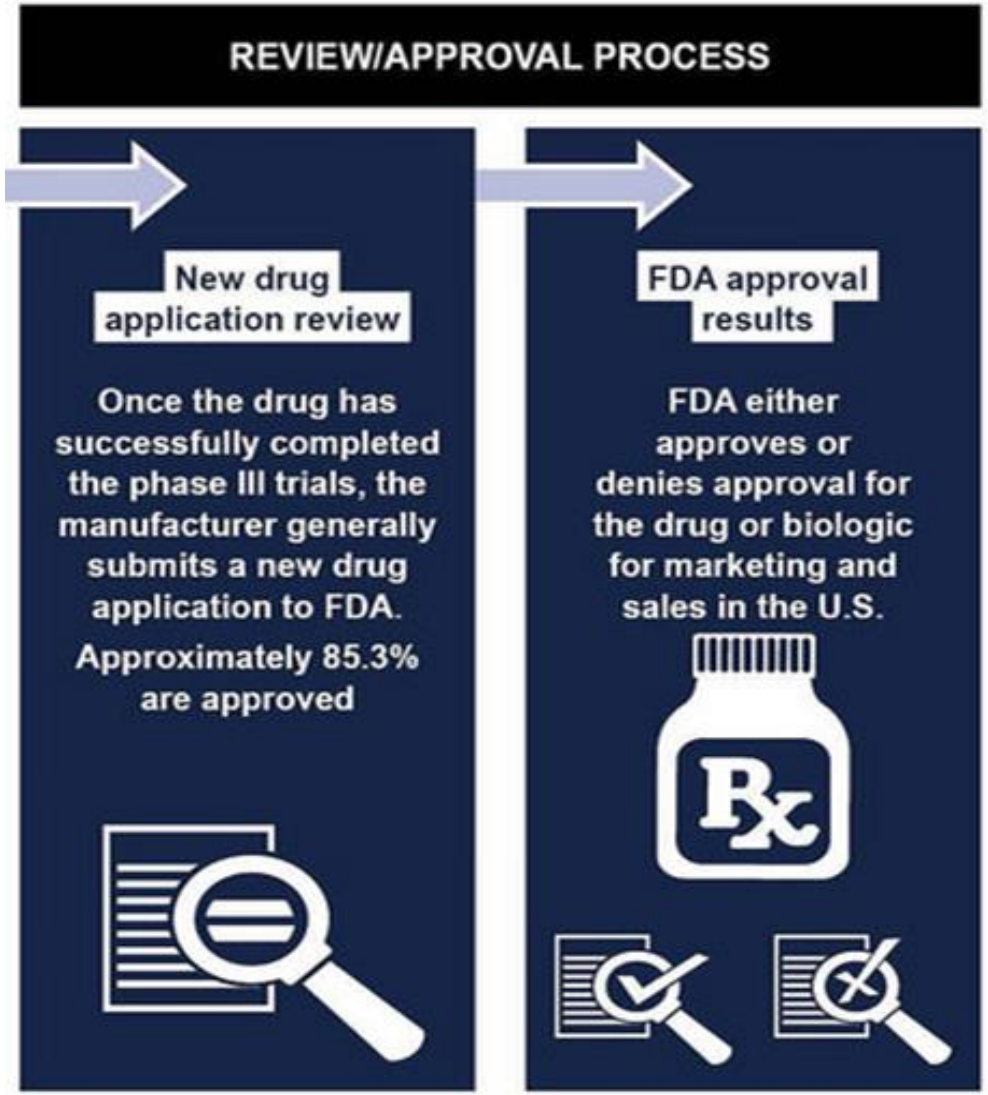
Phases of Clinical Drug Trials

- Bench Science
- Innovation

Phases of Clinical Drug Trials



Phases of Clinical Drug Trials



- https://www.fda.gov/patients/drug-development-process/step-3-clinical-research

Single-Patient Emergency Investigational New Drug

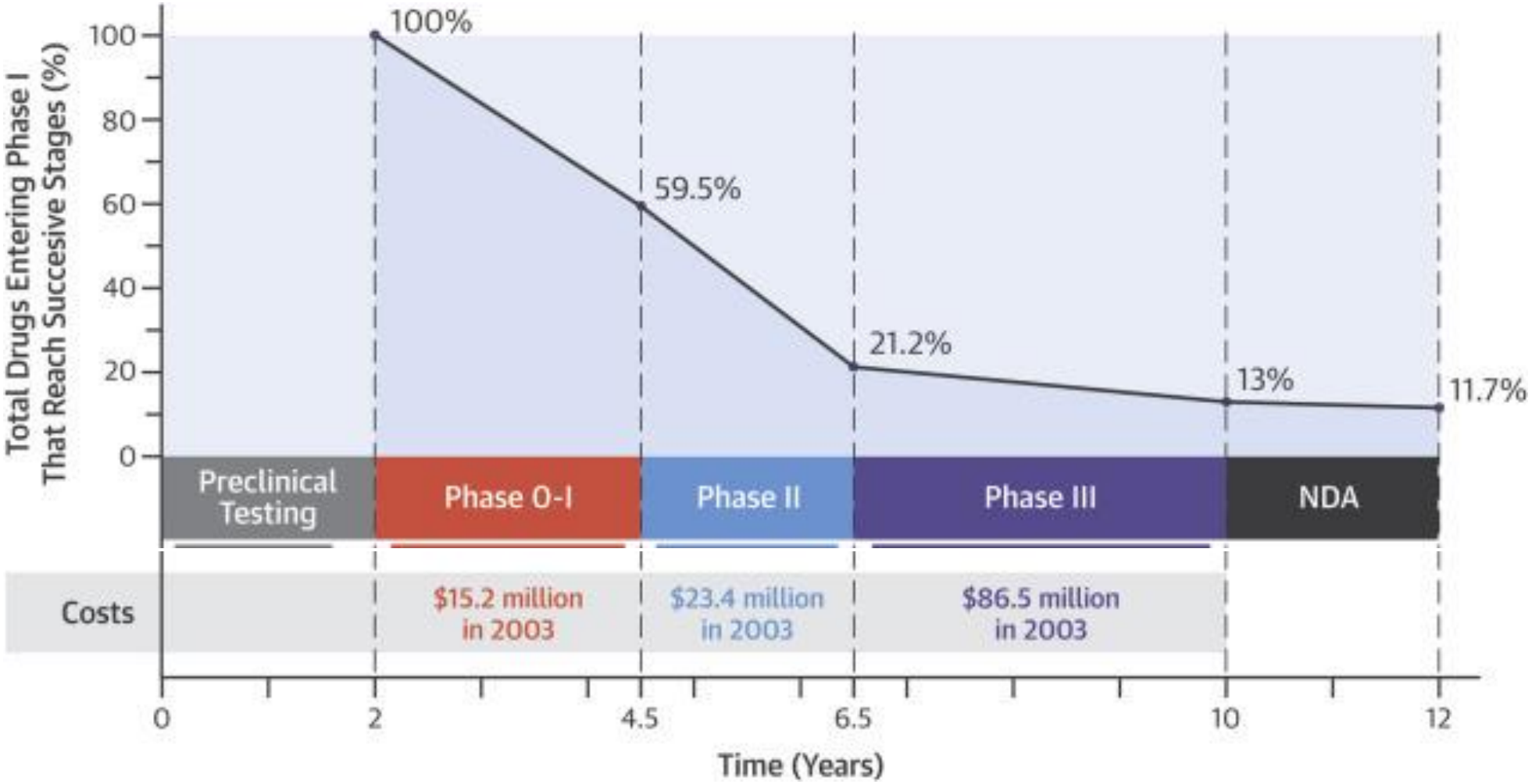
- Single-patient expanded access request
  - Commonly called “Compassionate Use”
  - Emergent & Non-emergency
- Phases I - III

https://www.fda.gov/news-events/public-health-focus/expanded-access

Survey Questions:

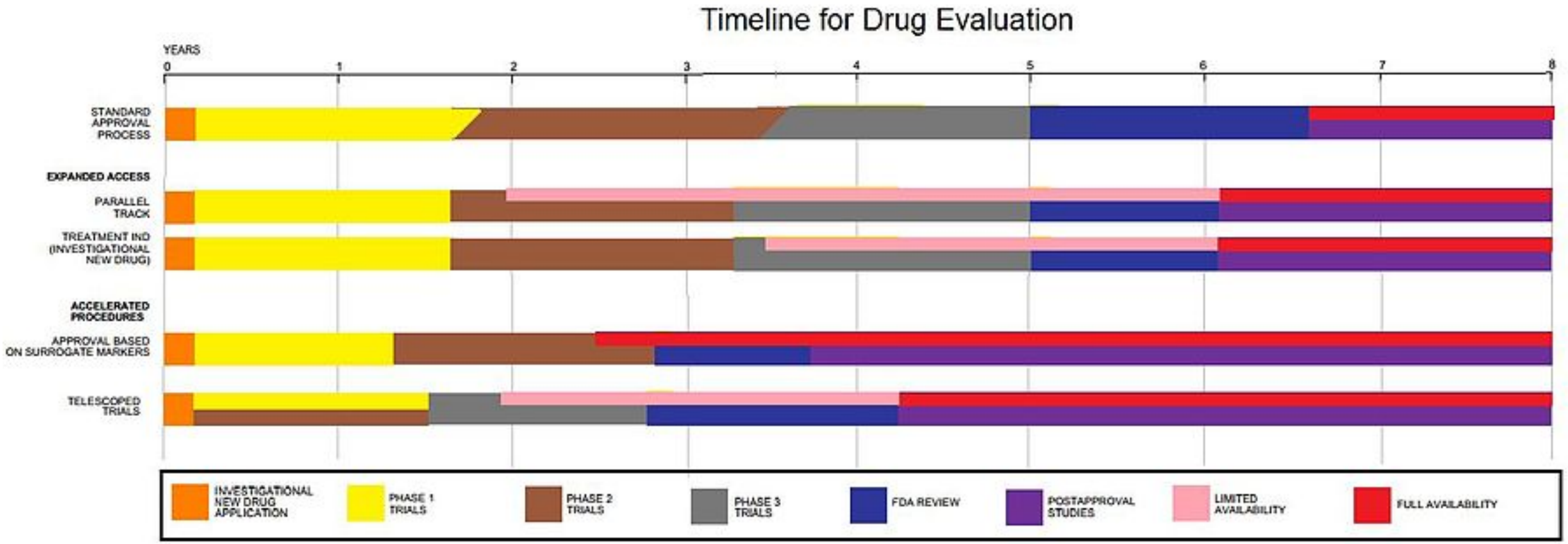
- Q: How long dose it take for an average drug to get to market.

- Q: How much does it cost to bring a new drug to market?

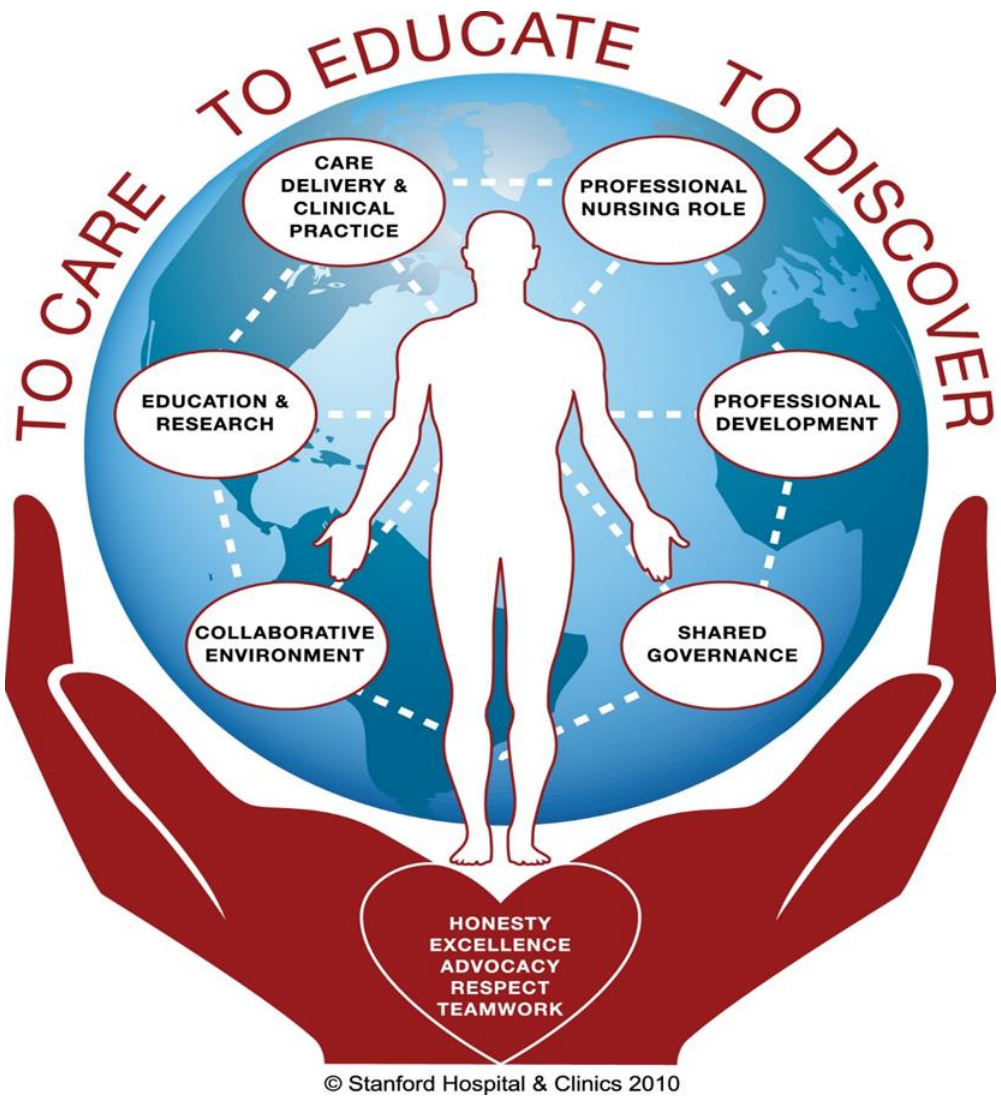


https://www.sciencedirect.com/science/article/pii/S2452302X1600036X#fig1

General Clinical Trial Time Line



Professional Practice Model



Care Delivery & Clinical Practice

STANDARD OF CARE NEEDS

PROTOCOL NEEDS

Care Delivery & Clinical Practice – Protocol Needs

SPECIMEN COLLECTION

DATA COLLECTION

ADMINISTRATION OF RESEARCH INTERVENTIONS

PATIENT ASSESSMENT

TESTS AND PROCEDURES

Care Delivery & Clinical Practice – Protocol Needs

Schedule of Study Procedures

	Screening	Check-in	Treatment				
			Days			Final Visit/ Early Termination	Unscheduled Visit (a)
Study Day	**-28 to -2**	**-1**	**1**	**2**	**3**	**4**	
Hour after dosing			**0**	**24**	**48**	**72**	
Informed consent/assent/HIPAA authorization (b)	X						
Inclusion/exclusion	X	X					
Medical history/demographics	X						
Concurrent medical conditions	X	X					
Complete physical examination	X	X				X	X
Vital sign measurements (c)	X	X	X	X	X	X	X
Height, weight, and BMI (d)	X	X				X	
12-lead ECG (e)	X	X	X			X	
Clinical laboratory tests (f)	X	X				X	
Fasting C-peptide (g)	X						
Blood glucose monitoring (h)			X	X			
Urine drug, cotinine and alcohol screens	X	X					
Serum Caffeine		X					
Serum pregnancy test (i)	X	X				X	
HBsAg and HCV tests	X						
PK blood sample (j)			**X**	**X**	**X**	**X**	
PD blood sample (k)			X	X			
PK urine sample (l)		X	X	X			
Confinement to clinic (m)		**X**	**X**	**X**			
Prior/concomitant medication assessment	X	X	X	X	X	X	X
Pretreatment/adverse event assessment (n)	X	X	X	X	X	X	X
Study drug administration			X				

Footnotes for Appendix A can be found on the following page.

- Source: https://irb.research.chop.edu/writing-protocol

Education & Research

- Standard of Care
- Protocol Requirements
- Side Effects
- How to Contact Study Team Member
- Discharge Instructions
  - SAEs

Patient Advocate

- Know Side Effects
- Report all Adverse Events
  - Even Minor Deviations from Defined Limits Should be Documented and Reported to the Study Team
- Close Patient Monitoring
- Comfortable asking questions
- Know where to escalate issues

Care Coordination / Collaboration

- Collaboration
  - Primary Team
  - Consult Services
  - Research Team
  - Supportive Services

  - Office of Research, PCS
  - Unit Leadership
- Communication

RN Role and Study Fidelity

- Reduction in Protocol Deviations
  - Missed Timepoints
  - Missed Procedure / Test
- Accurate Data Collection & Entry
- Processing Requirements
- Protocol Adherence
- Source Document

Ongoing COVID-19 Research

Vaccination and Treatment

To improve our ability to prevent COVID-19 and treat those infected.

Clinical trial of tocilizumab in hospitalized adults with severe COVID-19 pneumonia
Nidhi Rohatgi, MD, Kari Nadeau, MD, PhD, Neera Ahuja, MD

Rohatgi, Nadeau and Ahuja are conducting a randomized, double-blind, placebo-controlled phase 3 trial to evaluate the safety and efficacy of tocilizumab, an interleukin-6 receptor antibody, in hospitalized adult patients diagnosed with severe COVID-19 pneumonia. This multicenter trial is being conducted at 65 sites globally.

Clinical trial of remdesivir in hospitalized adults with COVID-19
Neera Ahuja, MD, and Kari Nadeau, MD, PhD

Nadeau and Ahuja are conducting a randomized, double-blind, placebo-controlled phase 2 trial to evaluate the safety and efficacy of the Ebola drug remdesivir in hospitalized adult patients diagnosed with COVID-19. The study is sponsored by the National Institutes of Health and is a multicenter trial that will be conducted at as many as 50 sites globally.

Phase 3 clinical trials of remdesivir in patients hospitalized with moderate and severe COVID-19
Aruna Subramanian, MD, and Philip Grant, MD

Subramanian and Grant have been conducting two multicenter, randomized, phase 3 clinical trials of an anti-viral medication, remdesivir. They are following patients to see how quickly they improve to the point of no longer needing oxygen or hospitalization. These trials, supported by Gilead Sciences, are being conducted at 100 centers worldwide. Stanford Medicine has been enrolling patients since March 14.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Remdesivir for the Treatment of Covid-19 — Preliminary Report

J.H. Beigel, K.M. Tomashek, L.E. Dodd, A.K. Mehta, B.S. Zingman, A.C. Kalil, E. Hohmann, H.Y. Chu, A. Luetkemeyer, S. Kline, D. Lopez de Castilla, R.W. Finberg, K. Dierberg, V. Tapson, L. Hsieh, T.F. Patterson, R. Paredes, D.A. Sweeney, W.R. Short, G. Touloumi, D.C. Lye, N. Ohmagari, M. Oh, G.M. Ruiz-Palacios, T. Benfield, G. Fätkenheuer, M.G. Kortepeter, R.L. Atmar, C.B. Creech, J. Lundgren, A.G. Babiker, S. Pett, J.D. Neaton, T.H. Burgess, T. Bonnett, M. Green, M. Makowski, A. Osinusi, S. Nayak, and H.C. Lane, for the ACTT-1 Study Group Members*

ABSTRACT

BACKGROUND
Although several therapeutic agents have been evaluated for the treatment of coronavirus disease 2019 (Covid-19), none have yet been shown to be efficacious.

METHODS
We conducted a double-blind, randomized, placebo-controlled trial of intravenous remdesivir in adults hospitalized with Covid-19 with evidence of lower respiratory tract involvement. Patients were randomly assigned to receive either remdesivir (200 mg loading dose on day 1, followed by 100 mg daily for up to 9 additional days) or placebo for up to 10 days. The primary outcome was the time to recovery, defined by either discharge from the hospital or hospitalization for infection-control purposes only.

RESULTS
A total of 1063 patients underwent randomization. The data and safety monitoring board recommended early unblinding of the results on the basis of findings from an analysis that showed shortened time to recovery in the remdesivir group. Preliminary results from the 1059 patients (538 assigned to remdesivir and 521 to placebo) with data available after randomization indicated that those who received remdesivir had a median recovery time of 11 days (95% confidence interval [CI], 9 to 12), as compared with 15 days (95% CI, 13 to 19) in those who received placebo (rate ratio for recovery, 1.32; 95% CI, 1.12 to 1.55; P<0.001). The Kaplan-Meier estimates of mortality by 14 days were 7.1% with remdesivir and 11.9% with placebo (hazard ratio for death, 0.70; 95% CI, 0.47 to 1.04). Serious adverse events were reported for 114 of the 541 patients in the remdesivir group who underwent randomization (21.1%) and 141 of the 522 patients in the placebo group who un-

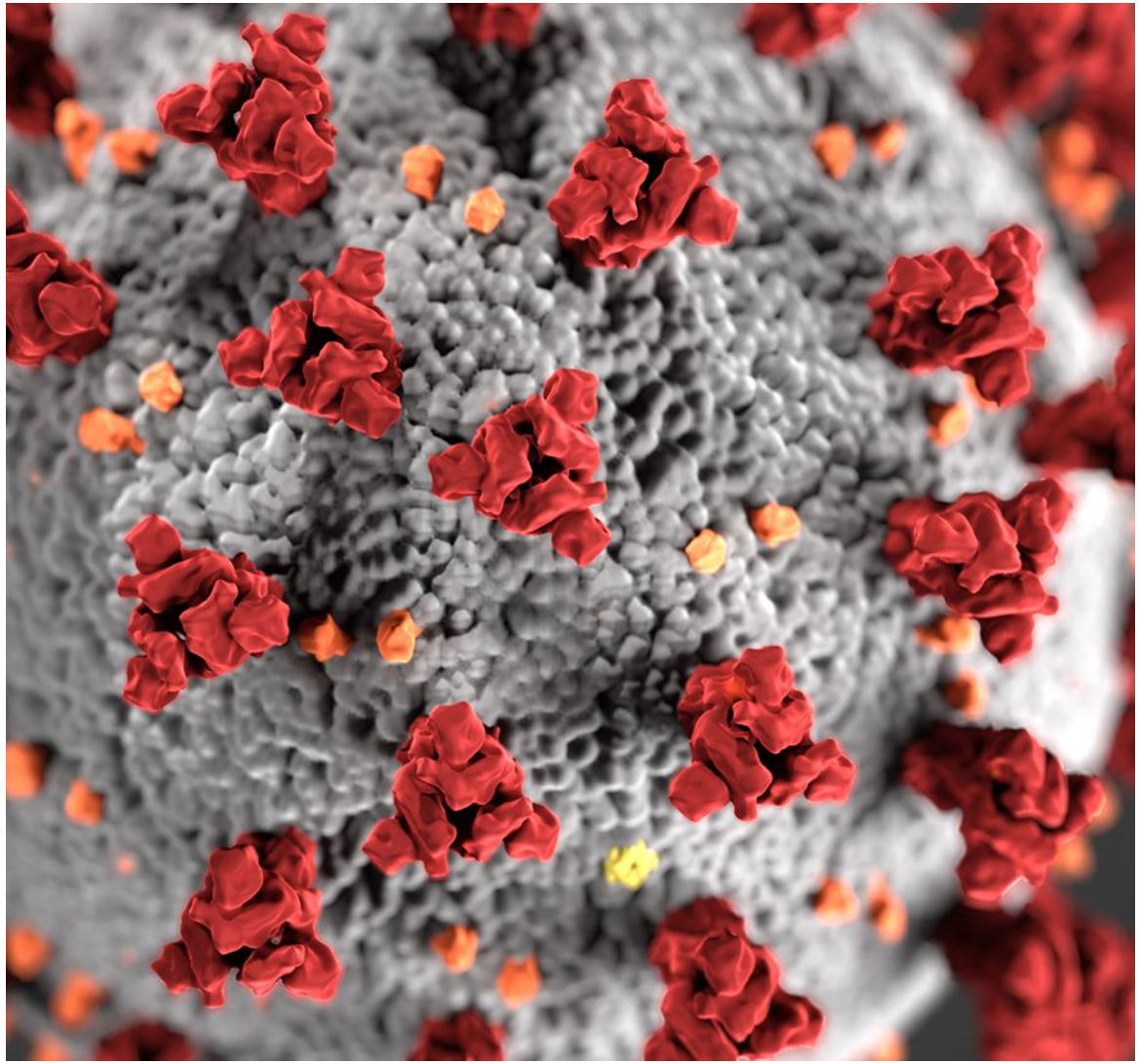
https://med.stanford.edu/covid19/research.html

RN Testimonials

- *“What I like about these trials is the hope that one day we would be able to come up with the best medication to fight COVID-19 infections. Also, RNs get to have knowledge about these medications especially their pharmacodynamics and pharmacokinetics.”*

Units With COVID Studies

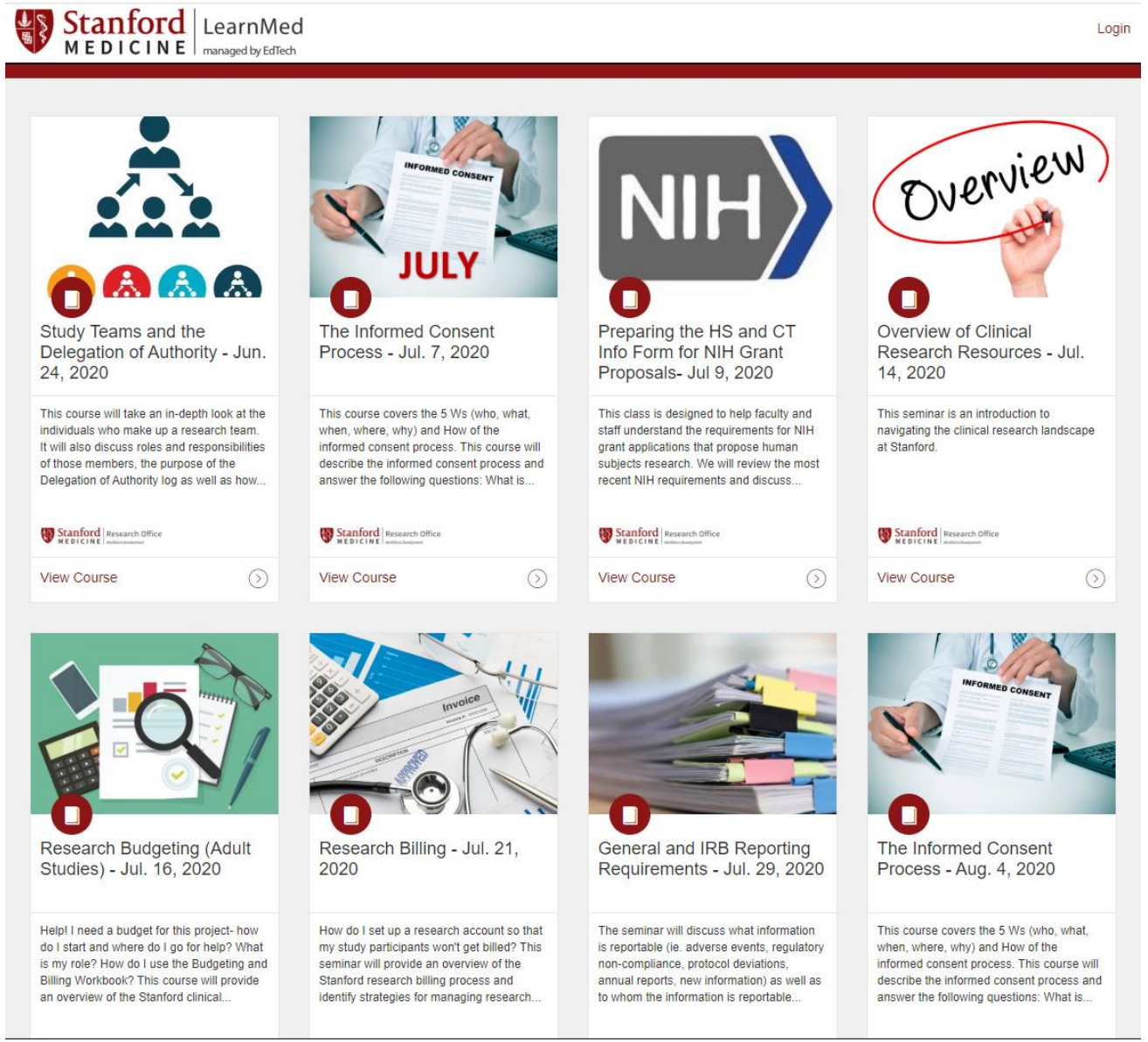
- ED
- K4
- M7
- Capacity For Expansion For Surge



Summary

- Differences in Research and Quality Improvement
- Various phases of clinical drug trials
- General time frame for most drug trials
- Contributions of the bedside nurse in clinical trials
- Key components of study fidelity

Other Educational Opportunities



https://catalog.learnmed.stanford.edu/browse/dm/stanford/research-office

Stanford Health Care
General Research Guidebook 2020

New Web Page

https://stanfordhealthcare.org/health-care-professionals/nursing/professional-excellence/orpcs.html

ORPCS Research Education Modules

Research Modules

A PART OF ORPCS EDUCATION

A video series on research literacy for clinical practice.

Research can often seem overwhelming and the process complex. Yet, research literacy and a fundamental understanding of the research process is required for optimal clinical care. Clinicians across the care spectrum are being asked to translate their clinical questions into structured research questions and incorporate existing research into their practice. The problem is that they may not know where to start or what the best practices are.

If you are new to research or looking to expand your knowledge, this is the place to start. This educational offering was graciously supported by the Stanford Nurse Alumnae. Stanford Nurse Alumnae are key supporters of nursing education and research-related activities at Stanford Health Care and contribute to the excellence of front-line clinical staff.

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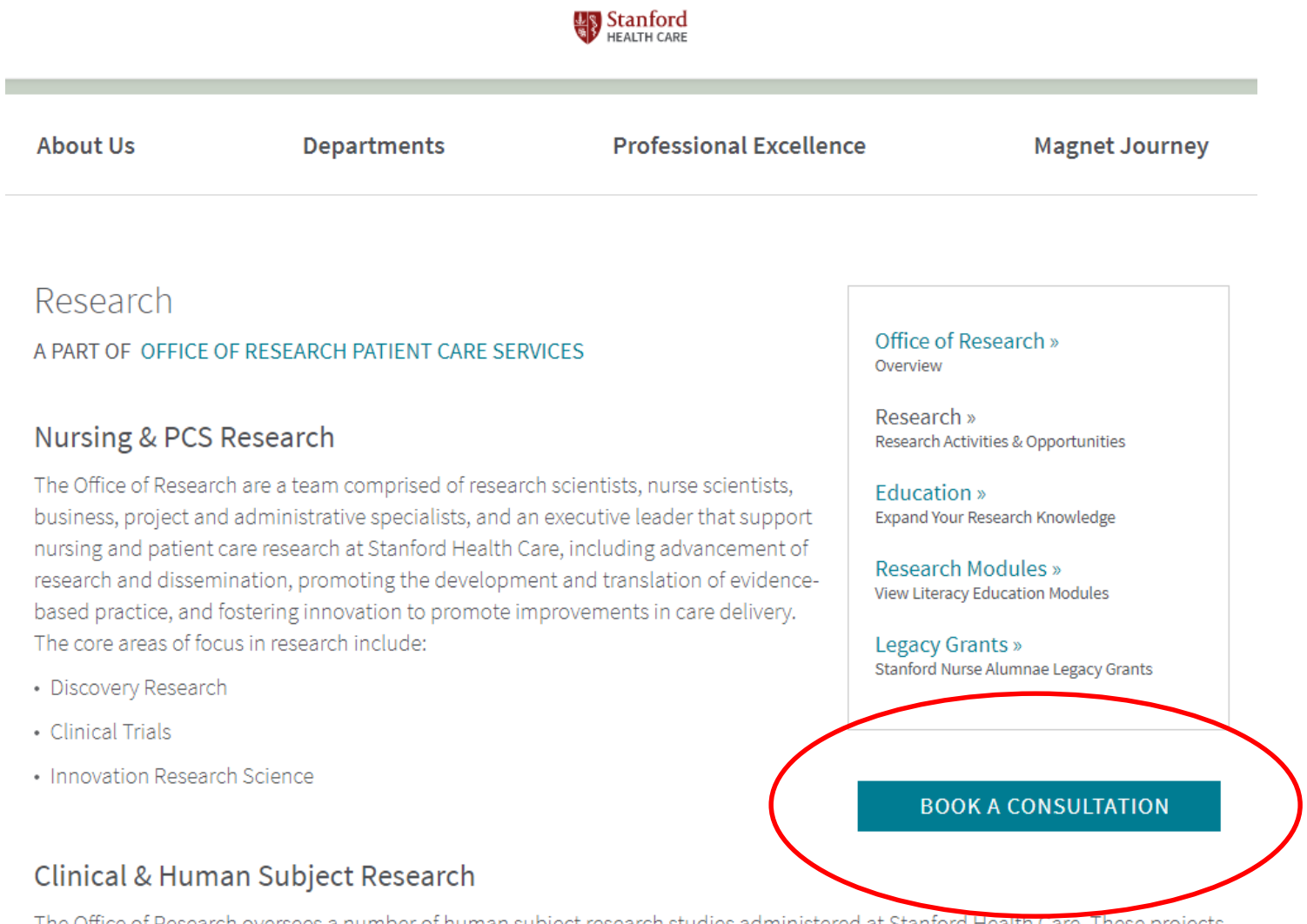
https://stanfordhealthcare.org/health-care-professionals/nursing/professional-excellence/orpcs/orpcs-education/orpcs-education-modules.html

Requesting a Consultation



https://app.smartsheet.com/b/form/a030e0d067214a23a046ea04976609ac

Stanford HEALTH CARE

Questions

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How to access complete your evaluation to get CE's (continued)

Complete Activity Evaluation & Access CE Certificate

Step 1: Click the "**My CE**" button on the top right side of the screen.

Step 2: Click "**Evaluations and Certificates**"

Step 3: **Complete the Evaluation** – Click the "**Complete Evaluation**" button

When the evaluation is completed the screen will re-load and a button will display that reads ***Download Certificate. A Copy of your certificate will be automatically emailed to you.***

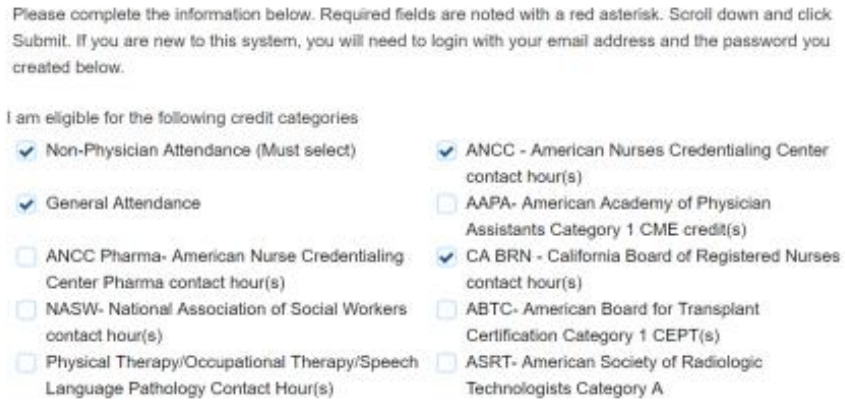
IMPORTANT: After receiving credit, certificates will be displayed in this area for 90 days. Please print or save any certificates within 90 days. CE certificate will drop off your MyCE profile and no longer be available after 90 days.

How to access complete your evaluation to get CE's

Update your profile to ensure you receive appropriate CE credits:

- Go to: www.cecenter.stanfordhospital.org
- Click on **CEPD Online Registration**
- Sign-In (non-SHC employee- use your email, SHC employee- use your SID)
- Click on **My CE** *(Mobile view may display images different than what is shown below)*

- Click on **Profile**
- Check appropriate credit categories to receive CE credits.



Certificates are issued to the attendee based on the "credit categories" selections you choose in your registration profile.