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2023
ACG IBD SCHOOL & SOUTHERN REGIONAL
POSTGRADUATE COURSE
DECEMBER 1-3, 2023 | RENAISSANCE NASHVILLE HOTEL
NASHVILLE, TENNESSEE
Register online: meetings.gi.org
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2024
ACG ENDOSCOPY SCHOOL &
ACG BOARD OF GOVERNORS /
ASGE BEST PRACTICES COURSE
JANUARY 26-28, 2024
ARIA RESORT
LAS VEGAS, NEVADA
ACG
ASGE
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3


MARCH 8-10, 2024
NAPLES GRANDE BEACH RESORT
NAPLES, FLORIDA
2024
EARN UP TO 12 CME CREDITS | EARN UP TO 12 MOC POINTS
ACG / FGS ANNUAL
SPRING SYMPOSIUM

4


2024
ACG/LGS REGIONAL
POSTGRADUATE COURSE
MARCH 1-3, 2024
DOUBLETREE BY HILTON NEW ORLEANS
NEW ORLEANS, LOUISIANA
Register online: meetings.gi.org
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THE CENTER FOR LEADERSHIP, ETHICS & EQUITY
CLINICAL RESEARCH LEADERSHIP PROGRAM
Application Deadline: November 10, 2023
Apply Online: gi.org/clinical-research-leadership

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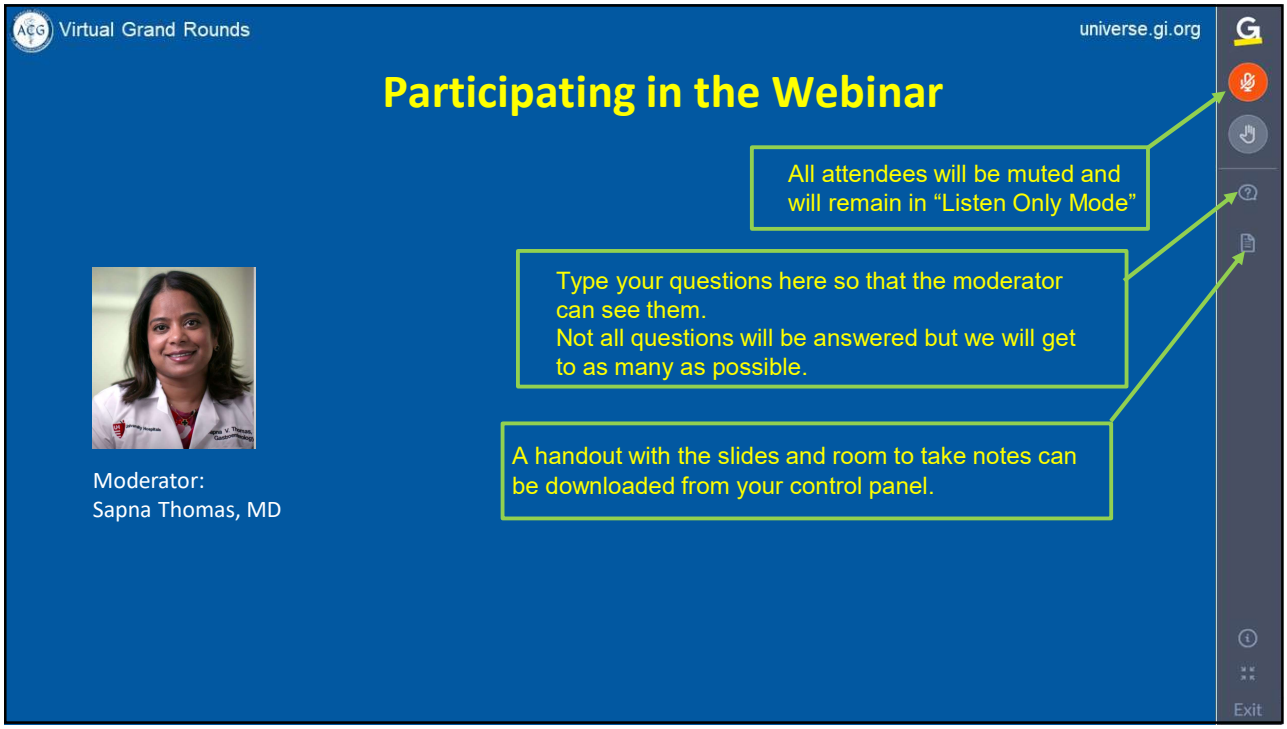
Those selected will be required to participate and complete the International Guideline Development Credentialing & Certification Program through McMaster University. The onsite training will be in Spring 2024 and is sponsored by the ACG. Applicants must agree to a 5-year term as a GRADE Methodologist.

7



8

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ACG Virtual Grand Rounds

Join us for upcoming Virtual Grand Rounds!


Week 46 – Thursday, November 16, 2023
Hemochromatosis
Faculty: Manida Wungjiranirun, MD
Moderator: Rebecca G. Kim, MD
At Noon and 8pm Eastern

There will be NO VGR on November 23 for Thanksgiving

Week 48 – Thursday, November 30, 2023
Management of Duodenal and Ampullary Polyps and Cancer
Faculty: Gregory B. Haber, MD, FACG
At Noon and 8pm Eastern

Visit **gi.org/ACGVGR** to Register

9

ACG Standard Slide Decks

Colorectal Cancer Screening and Surveillance Slide Deck
Ulcerative Colitis Slide Deck

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10

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Disclosures

Deepinder Goyal, MD MSCR:
Advisory board for Ardelyx Pharmaceuticals

Shajan Peter, MD, FACG:
No disclosures with any ineligible company.

Sapna Thomas, MD:
No disclosures with any ineligible company.

Whit Knapple, MD:
Participated in Pharmaceutical Research

**All of the relevant financial relationships listed for these individuals have been mitigated*

11

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Pharmaceutical and Device Research: A Win-win for your Patients and your Practice

Deepinder Goyal, MD MSCR

Shajan Peter, MD, FACG

12

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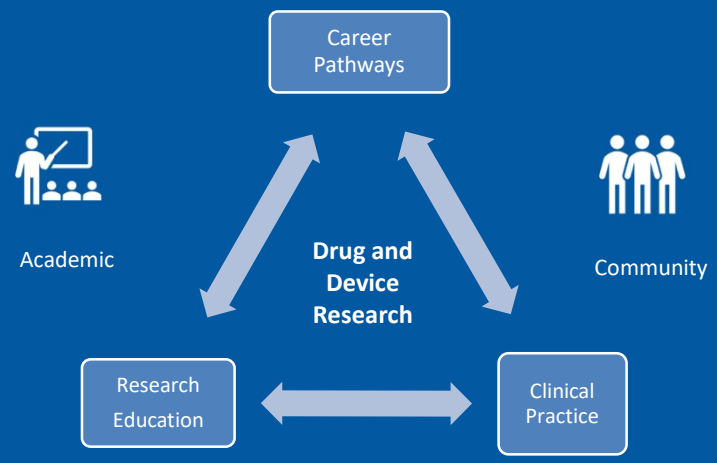
Introduction



13

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Introduction – What is the need?

Clinical trials often close prematurely because of inadequate accrual.

In 2020, 41% of Americans reported not knowing anything about clinical trials.

Reducing barriers to trial participation would ensure more generalizable and timely data on new treatments, allowing them to be made safely available to the public sooner.

Structural, clinical, attitudinal, and socioeconomic factors can affect clinical trial participation.

Certain populations, including older individuals, racial/ethnic minority groups, individuals with comorbidities, those of lower SES, and residents of rural areas are often underrepresented in clinical trials.

14

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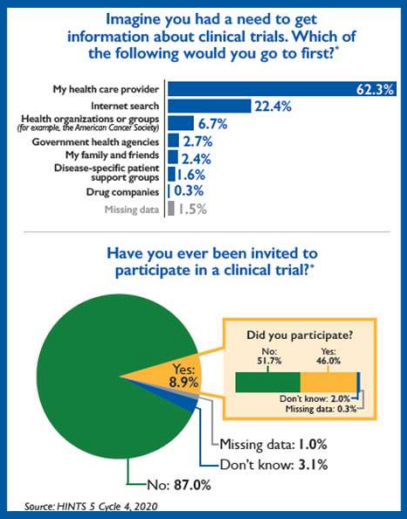
Clinical Trial Participation Among US Adults



- Lack of diversity in patient participation in clinical trials.
- Extrapolation of trial results to general population can be undermined.
- Evidence suggests clinician recommendation improves patient participation.
- Engagement of community physicians in clinical trials – key strategy to improve patient participation.
- Barriers for community clinicians participating in clinical trials exist.

NEJM 385;15 nejm.org October 7, 2021

NIH National Cancer Institute Division of Cancer Control & Population Sciences

15

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What to consider when planning to do research?

BENEFITS AND BARRIERS FOR BOTH PARTICIPATING PHYSICIANS AND PATIENTS

ASPECTS TO CONSIDER BEFORE ADDING CLINICAL RESEARCH INTO YOUR PRACTICE

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Is Industry-sponsored Research Right for my Practice?

17

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Benefits to Practice & Physicians

- Recruitment of physicians with research interests in private practice
- Build data repository
- Development of centers of excellence in non-academic settings
- Academic growth, advancement of knowledge & intellectual stimulation
- Improves patient care of existing patients
- Attract patients and allow growth in practice
- Financial incentive from value-based patient's contracts improving patient outcomes and cost of care
- Additional direct source of revenue: diversify revenue streams

18

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Benefits to Patients

- Availability to experimental therapies & devices
- Access to expensive medications
- Local availability to new and emerging medical interventions
- Boost monitoring and focus on clinical care
- Permit patients to contribute to advancement in medical field.
- Allows minorities to gain medical access with involvement of community-based private practices in clinical research
- Enhance patient understanding of their disease

19

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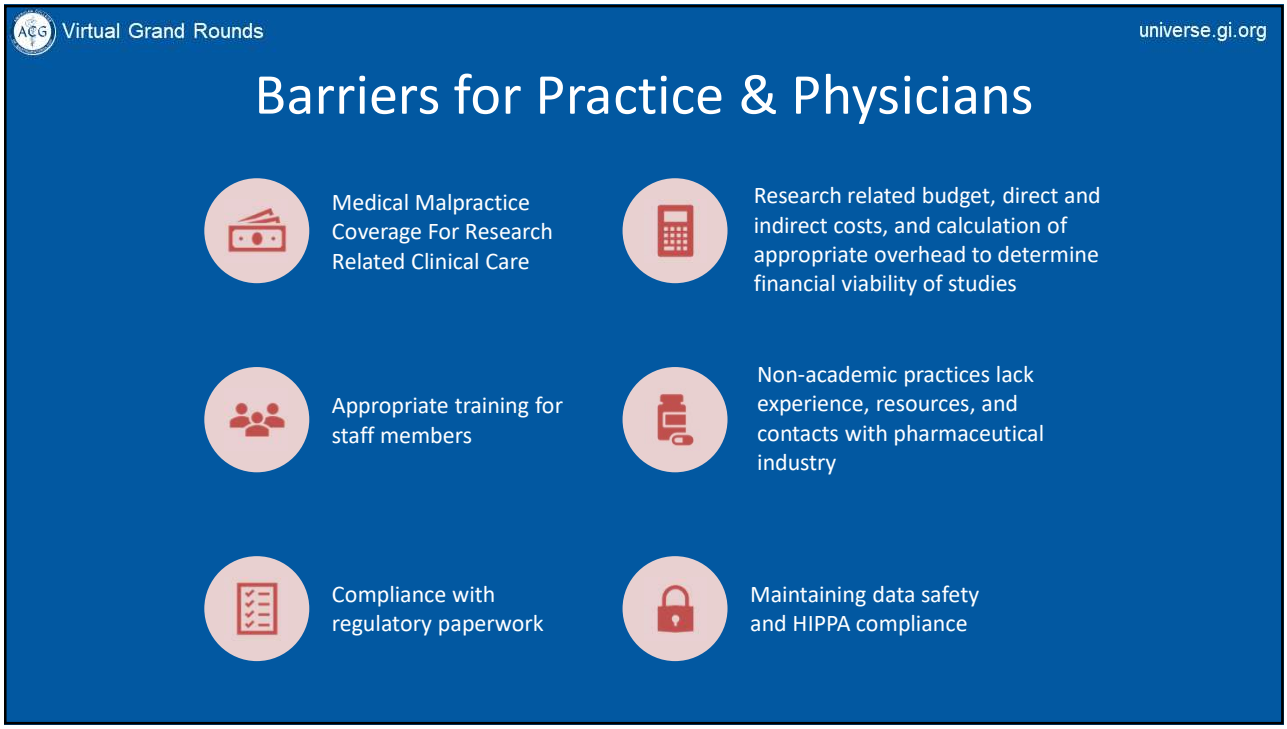
Barriers for Practice & Physicians …

Research Infrastructure

Time Commitment

Disruption In The Routine Practice Flow

20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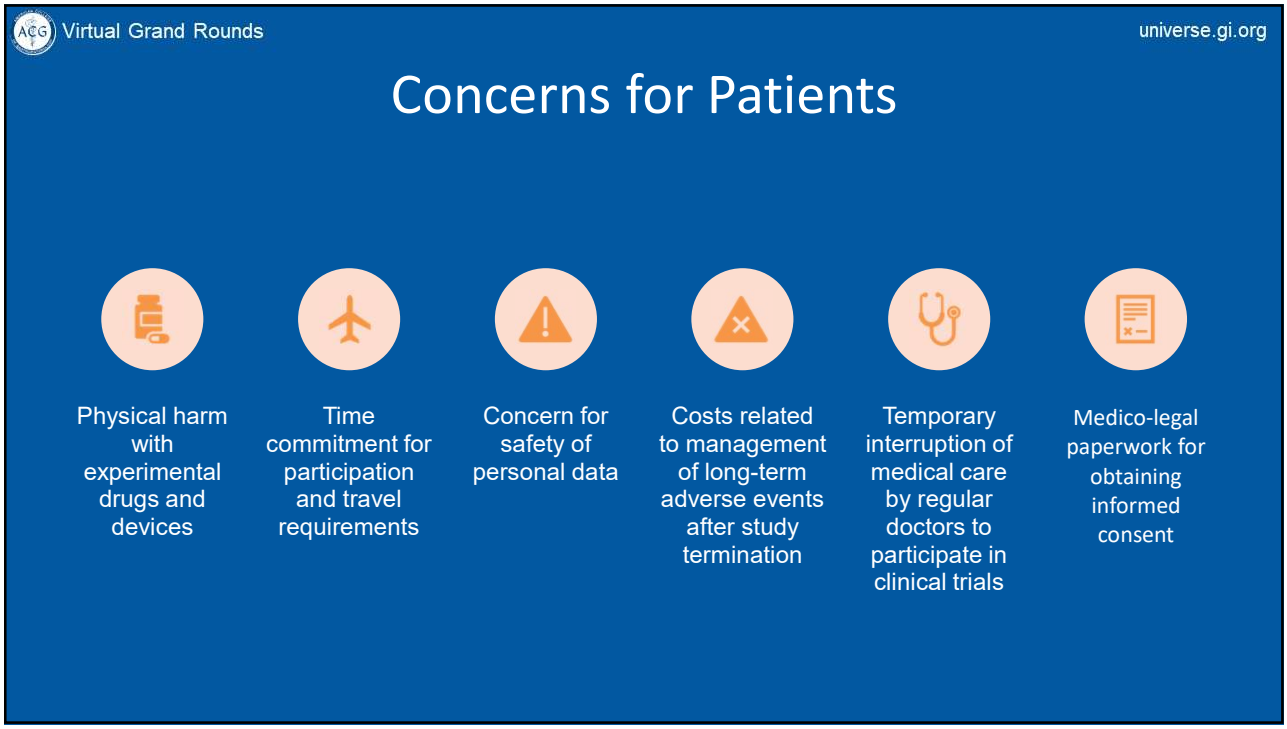
Barriers for Practice & Physicians
Medical Malpractice Coverage For Research Related Clinical Care
Research related budget, direct and indirect costs, and calculation of appropriate overhead to determine financial viability of studies
Appropriate training for staff members
Non-academic practices lack experience, resources, and contacts with pharmaceutical industry
Compliance with regulatory paperwork
Maintaining data safety and HIPPA compliance

21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Concerns for Patients
Physical harm with experimental drugs and devices
Time commitment for participation and travel requirements
Concern for safety of personal data
Costs related to management of long-term adverse events after study termination
Temporary interruption of medical care by regular doctors to participate in clinical trials
Medico-legal paperwork for obtaining informed consent

22

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Key Concepts and Checklist

23

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Feasibility Analysis

- Collective interest physicians, physician leaders and administrative staff
- Site analysis
  - Staffing needs
  - Equipment assessment
  - Patient database and referrals
- Market demand/competition
- Time commitment
- Training needs
- Travel requirements

24

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Determine Choice of Field and Type of Research

Most industry sponsored research :

Phase III (compares new to existing treatment) or

Phase IV (evaluates long-term benefits & side effects)

Choice of study depends upon number of factors:

Local expertise	Sub-specialty interests	Disease specific patient base of practice	Type and level of clinical and research infra-structure in place	Available resources	Practice compensation model	Availability of studies open for enrollment

25

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Requirements to Initiate Clinical Research Program

- Administrative and regulatory requirements
- Protected time out of busy clinical schedules
- Personal effort and time commitment needed to communicate with sponsor and review/sign contracts
- Obtain practice commitment to provide resources, administrative support and protected time
- Specialized software programs for data collection, maintenance, and submission.
- Fiscal planning
- Contractual and legal obligations
- Understand local and national insurance related policies for coverage of patients participating in clinical trials

26

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Budgetary Considerations for Clinical Research

Category	Types of Costs
Labor costs	Physician honoraria, Research coordinator salary, Biostatistics fees
Site Overhead	Building rent and utilities
Participant costs	Recruitment and travel stipend
Clinical care	Office visits, Procedures, Labs, Imaging
Material costs	Drugs, Equipment, Test kits, Shipping, Storage of samples
Data Management	Data capture and storage software
Miscellaneous	Advertising, Travel, Meetings

27

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Trial Participation Start-Up Activities

- Contract negotiations
- Institutional review board (IRB) Submission
- Budget agreement
- Equipment allocation
- Set up vendor services
- Physician and research staff training
- Investigator agreements
- Form FDA 1572
- Site initiation visit and portal set-up

28

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Organize Integrated Clinical Research Team

- Assemble research team: study site management staff, study investigators, clinical research coordinators, regulatory personnel, financial personnel, and contract/legal experts.
- Acquire basic or advanced clinical research training online or live courses
- Training resources include Association of Clinical Research Professionals (ACRP) and Certified Clinical Research Professionals Society (CCRPS)
- Clinical staff involved in research needs training in good clinical practice through NIH (http://grants.NIH.gov) or CITI program (http://about.citiprogram.org)

29

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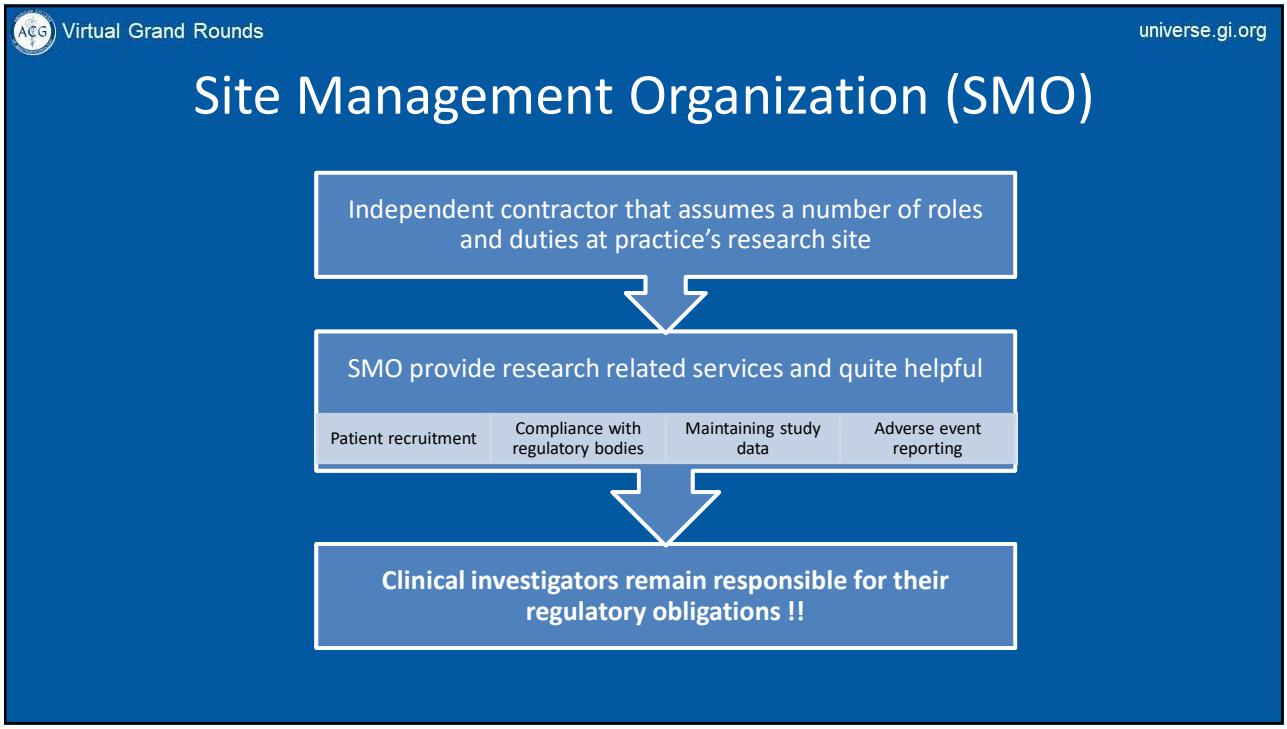
Industry Sponsored Multi-Institutional Studies

- Principal investigator in coordination with study sponsors assist with approval of study protocol, informed consents, budget, and local or central IRB
- Often Contract Research Organization (CRO) assumes duties of the study sponsor by an independent legal contract
- Study site responsible for adhering to good clinical practice, NIH HIPPA guidelines, and FDA regulations
- Clinical investigator at study site has primary responsibility to ensure patient safety and protect their rights/welfare

30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Site Management Organization (SMO)
Independent contractor that assumes a number of roles and duties at practice's research site
SMO provide research related services and quite helpful
Patient recruitment
Compliance with regulatory bodies
Maintaining study data
Adverse event reporting
Clinical investigators remain responsible for their regulatory obligations !!

31


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Responsibilities of Principle Investigator (PI)
Protect the rights, safety, and welfare of subjects
Ensure informed consent is obtained
Compliance with study protocol, IRB, FDA regulations
Disclose any conflicts of interest
Maintain accurate, complete, and up-to-date study records
Submit progress and safety reports
Oversee investigational product
Maintain a log for delegation of responsibilities

32

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Collaborate with Management Service Organization (MSO)

- Central hub workflow
- Launch and accelerate participation in multi-site trials
- Centralize administrative support services: regulatory, research coordinator, credentialing, physician training, financial, hiring
- Universal platform to capture key research data
- Rapid expansion with access to multiple and better studies
- Beware of associated costs

33

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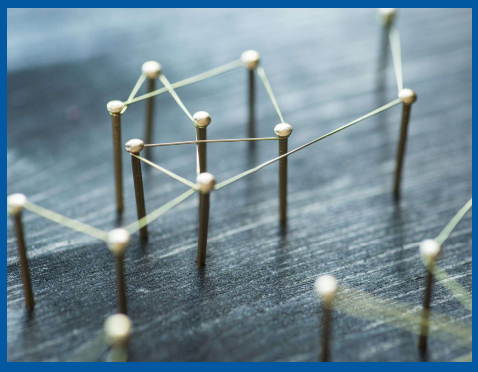
Consider Collaborating with an Academic Research Institution

- Helps a practice navigate training, expertise, trial evaluations, acquisition, compliance and regulation control and overall guidance
- Helpful if undergoing an FDA audit
- Assist a program become bigger and more efficient
- Facilitates collaboration among different medical practices, researchers and healthcare professionals
- Exchange of ideas and sharing resources : e.g. negotiating budget



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Central Trial Management System (CTMS)

- Central repository
- Study design, planning and execution
- Track regulatory documentation
- Management of study team and suppliers
- Clinical monitoring of patients
- Invoices, stipends and investigator payments

35

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Identify healthcare industry sponsor

Search active trials in local area fitting interests, timeline and requirements of practice at the FDA website (ClinicalTrials.gov)

U.S. National Library of Medicine ClinicalTrials.gov

Network with other clinical research sites

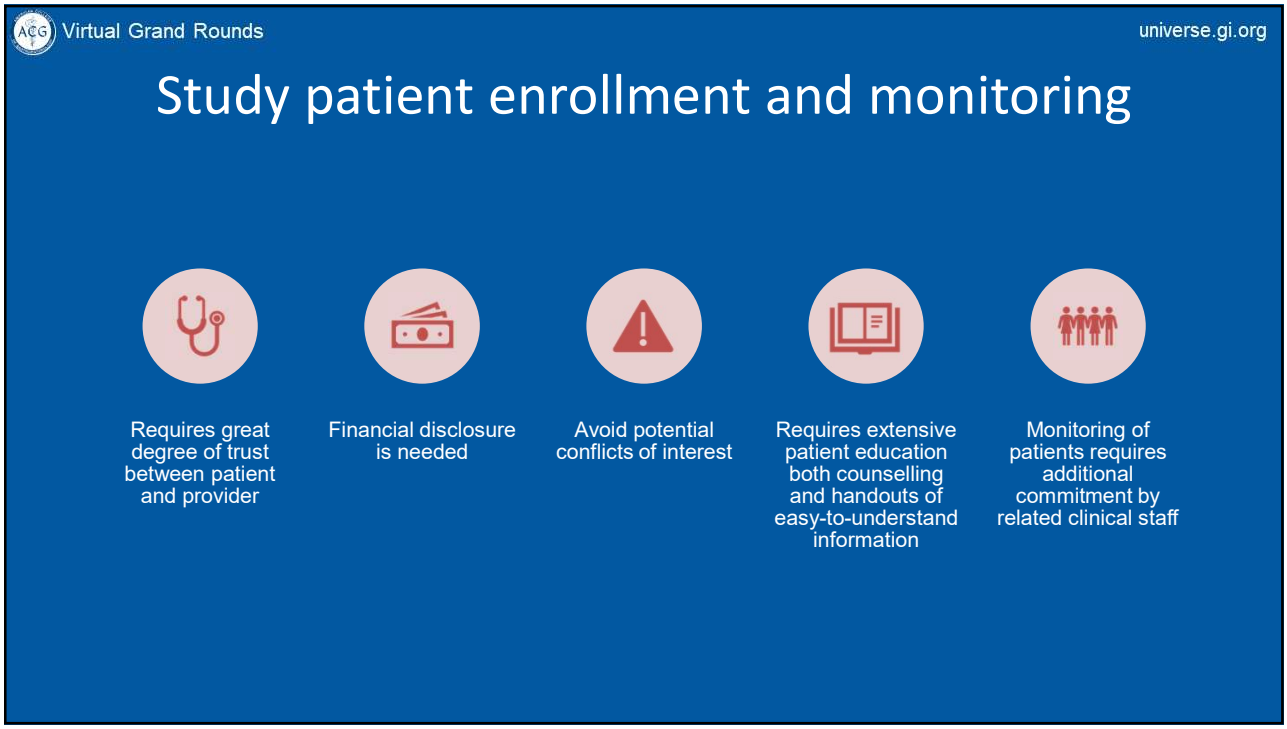
Interact with fellow physicians, pharmaceutical and device sales representatives, and medical scientific liaisons

Contact third party clinical research companies

Enlist your practice in a Clinical Research Organization (CRO) database

Easy to recruit, not labor-intensive studies) have to be performed to gain experience and a record of accomplishment

36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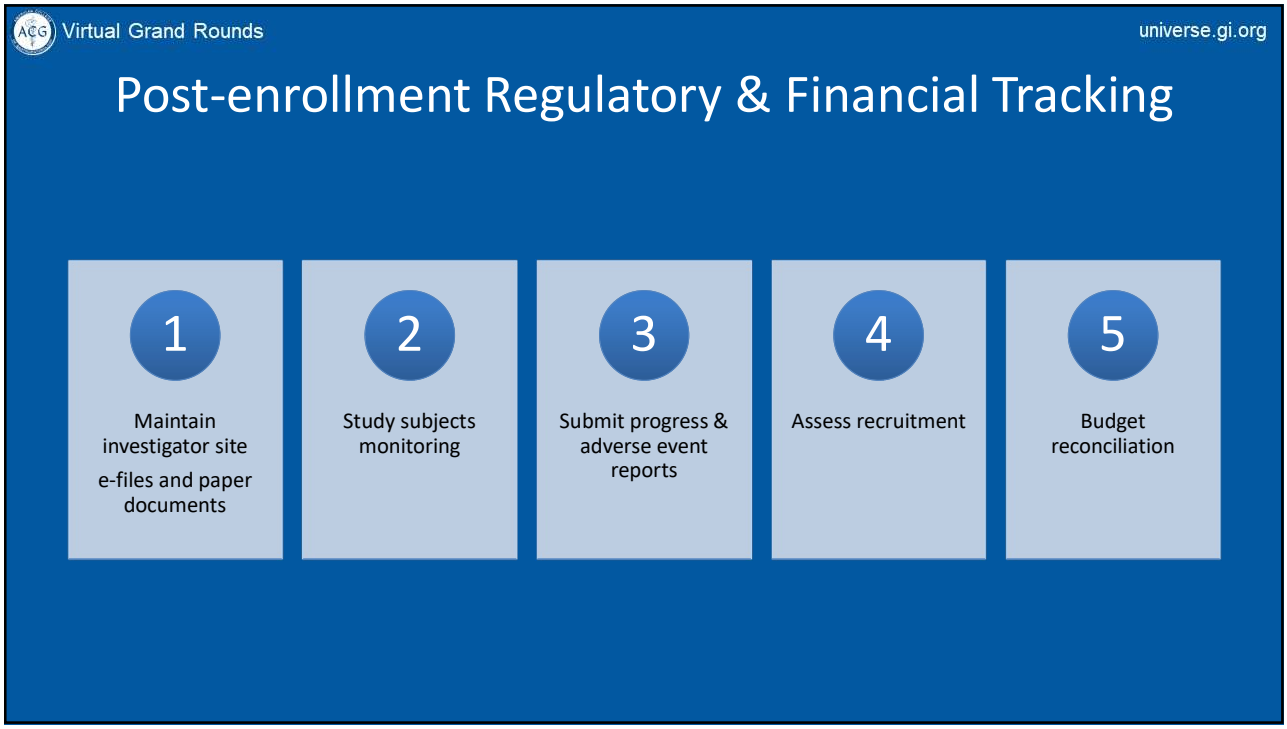
Study patient enrollment and monitoring
Requires great degree of trust between patient and provider
Financial disclosure is needed
Avoid potential conflicts of interest
Requires extensive patient education both counselling and handouts of easy-to-understand information
Monitoring of patients requires additional commitment by related clinical staff

37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Post-enrollment Regulatory & Financial Tracking
1
Maintain investigator site
e-files and paper documents
2
Study subjects monitoring
3
Submit progress & adverse event reports
4
Assess recruitment
5
Budget reconciliation

38

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Study outcomes

Dissemination of study results to participating patients, providers and authorship on any resultant publication should be agreed upon at the time of initial contract agreement

Some studies will hold back revenue until the study is closed

Important goal is to limit holdbacks to only your site and not all sites, as you cannot control other site quality or data acquisition

39

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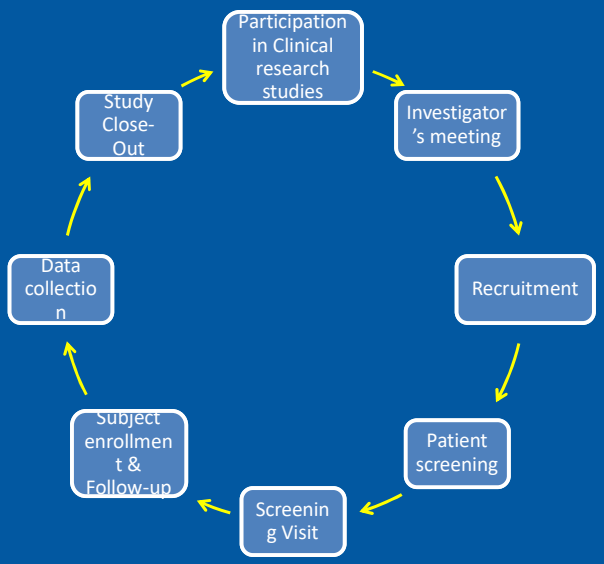
General Flow of a Study



40

Conclusion

- Participation of clinicians in research enhances advancing medical research and improving patient care.
- Require dedicated time for physician investigators, research personnel, continued training for good clinical practice (GCP).
- Expand medical research access to diverse patient populations furthering outreach.
- Provides mutual benefits to both patients and their treating physicians, a win-win for all.

41

Thank you!

Q&A

42

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Questions

Deepinder Goyal, MD MSCR

Shajan Peter, MD, FACG

Sapna Thomas, MD

Whit Knapple, MD

43

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44