We will begin shortly.

For those in-person wifi access information below
Network = JWMarriot-conference
Password: meeting2022
WELCOME ALL

THRIVE
I have no conflicts of interest to declare.
CONGRATULATIONS

Sachin Kheterpal, MD, MBA

ELECTED TO

National Academy of Medicine

Kevin K. Tremper Research Professor,
Department of Anesthesiology
Closed

Phased Large Awards for Comparative Effectiveness Research – Cycle 3 2020

RESEARCH Cycle 3 2020

Research Initiative Highlights

This PCORI funding announcement invites applications for high-quality comparative effectiveness research (CER) projects that will examine a critical patient-centered research question that is also relevant to decision makers and other stakeholders. For this PFA, investigators should propose an individual-level or cluster randomized controlled trial of significant scale and scope, requiring funding in excess of $10 million in direct costs. The proposed trials should address important decisional dilemmas that require important new evidence about the comparative effectiveness of available interventions. Proposed studies should compare interventions that already have established evidence of efficacy or are in widespread use. Clinical interventions (such as medications, diagnostic tests, or procedures) and delivery system interventions are appropriate for study.
THRIVE: Trajectories of Recovery after Intravenous Propofol vs inhaled Volatile anesthesia

Clinical Trials Network (IMPACT)

This award was established by leaders of academic anesthesiology organizations that recognized there was a need to conduct large pragmatic trials in order to answer important questions in anesthesiology-related research.
Welcome
Our journey here

Mar 7, 2020

Michael & Sachin discuss ideas for LOI

Sep 29

Oct 27

LOI submitted, then approved
THRIVE - Version 1.0

**Figure 1: THRIVE trial study design**

- **TIVA**
  - Stratified
  - Individual Randomization
  - Across 6 Centers
  - N = 15,000

- **INHALED**

**EFFECTIVENESS OUTCOMES & BENEFITS**
- Recovery – QOR15
- Disability – WHODAS 2.0
- Delirium – 3DCAM
- Activity

**DAILY WEARABLE SIGNALS**

**SAFETY OUTCOMES & SIDE EFFECTS**
- Awareness with recall - BRICE
- Kidney injury
- Myocardial Ischemia
- Mortality

**Timeline:**
- Day 0
- Day 1
- Day 2
- Day 30
- Day 90

**LOI:** September 29th 2020
Our journey here

Mar 7, 2020

Michael & Sachin discuss ideas for LOI

Sep 29

LOI submitted, then approved

Oct 27

Team assembled, full proposal submitted

Jan 12, 2021

PCORI announces THRIVE award. Budget and proposal updates begin

Jul 27, 2021

Official contract start

Jan 1, 2022

First Patient Randomized

Sep 6

Investigator launch meeting

Today
THRIVE team members

Here today in person

Michael Avidan
Mara Bollini
Michael Burns
Hugo Campos
Chelsea Cloyd
Nicole Eyrich
Allison Janda
Sathish Kumar
Sachin Kheterpal
Mark Neuman
Bethany Pennington
Amy Price
Nirav Shah
Laura Swisher

Here in spirit (or digitally)

Arbi Ben Abdallah
Sarah Buday
Jennifer Carron
Larry Chu
David Clark
Douglas Colquhoun
Ralph Dacey
Mark Dehring
Stephen Gregory
Bruce Hall
Melissa Hicks
Katie Holzer
Rose Ignacio
Heidi Klosterman
Amy Krambrink
Meghan Lane-Fall

Here in spirit (or digitally)

George Mashour
Bernadette Peters
Mary Politi
Christie Ramirez Rodriguez
Linda Robison
Michelle Romanowski
Anik Sinha
Cathie Spino
Steve Thelen Perry
Brian Torres
Shelly Vaughn
Phil Vlisides
Zhenke Wu
Andrew Zittleman
Thank you for..

Your commitment and support since the beginning of this journey

Your frank feedback

Your impact on the protocol

Your trust

Your resources

Your local political capital
The Clinical Coordinating Center (CCC) and the Data Coordinating Center (DCC)

Laura Swisher and Chelsea Cloyd
The Clinical Coordinating Center (CCC)

Washington University School of Medicine
Clinical Coordinating Center: Study Support

1. General Oversight of site performance and clinical issues
2. sIRB management and coordination with performance sites
3. Management of SAE reporting and review, in conjunction with the DCC
4. Maintenance of documentation (DOA, Licensure, training certificates, etc.)
5. Continued training for new study members
6. Escalation of unexpected issues and performance concerns
7. Will guide site adoption of any protocol or process changes
Clinical Coordinating Center: Study Support

- Monthly calls to sites after activation will cover
  - Enrollment numbers and demos
  - Regulatory
  - Protocol adherence (study arm compliance, withdrawal #s, deviations, etc.)
  - Help troubleshooting issues as needed
- Available on an “as needed” basis to help site achieve study goals
- Laura Swisher, Program Manager, goodl@wustl.edu
Clinical Coordinating Center: Activation Support

- The CCC can provide suggestions on clinical stakeholder educational and informational session outreach
  - Template slide decks for clinician educational and informational sessions available

**Clinical Infrastructure**

- Relevant TIVA educational documents reviewed
- Availability of processed EEG monitors, TIVA technical infrastructure confirmed
- Informational sessions planned for institution stakeholders (surgeons, CRNAs, Nurses, etc.)
Clinical Coordinating Center: Activation Support

- Will provide MOP and Protocol training for relevant, engaged study team members
- Will track training and work with the DCC to schedule MQUARK and MyDataHelps training
- Will ensure all training is complete and help sites meet this goal
Clinical Coordinating Center: Activation Support

- The CCC will help manage and troubleshoot site application to WUSTL single IRB (sIRB)
- Collection of documents required for GCP will be overseen by the CCC
Phase 1:
Begin Patient Enrollment
U of M and WUSTL
August 1, 2023

Phase 2:
Next 8 Sites Onboarded
November 30, 2023

Phase 3:
Remaining Sites Onboarded
February 29, 2024

Full Scale Study End
June 30, 2028

Complete Patient Enrollment
August 1, 2027

Peer Review and Report Writing Period
July 2028- June 2029
The Data Coordinating Center (DCC)
DCC Components
DCC Core Responsibilities

1. Data collection software
2. Support, training, and access
3. Operational Reports
4. Data validation and quality assessment
5. MPOG data flow

In partnership with SABER:

1. DSMP and DSMB
2. Randomization mechanism
3. Statistical analysis plans
Data Sources

- **MQUARK**
  - Research Coordinators
  - Coordinator Entered Data
    - Screening, approach, consent data
    - Study workflow
    - Randomization allocation
    - Reminder/Follow up contacts

- **MyDataHelps**
  - Patients
  - Participant Provided Information
    - Digital copy of informed consent
    - Baseline surveys
    - Patient reported outcomes
    - Wearable data

- **MPOG Import Manager**
  - Clinicians
  - Electronic Health Record
    - Clinical data (diagnoses, surgical procedure details, lab values)
    - Propofol TIVA vs Inhaled Volatile protocol adherence
    - Safety outcomes

---

**THRIVE Central Database**

- Data Quality Diagnostic
- Trial Operational Metrics
- Analytical Dataset
Purpose and study details:

The purpose of this research is to learn whether and how early data on outcomes following surgery can inform the design of future research studies. Two common types of outcomes following surgery are collecting electronic health data (e.g., medical records) and gathering data using apps on personal digital assistants and smartphones. Your participation is voluntary, and you can withdraw from the study at any time without penalty. The study is funded by the National Institutes of Health and the National Institute on Aging.

Outcomes Research, a non-profit, independent nonprofit organization in the United States, is coordinating this study. If you have any questions about the study, please contact the Study Coordinator or the Research Team Contact listed below.

Participant Provided Information:

- **Digital copy of informed consent**
- **Baseline surveys**
- **Patient reported outcomes**
- **Wearable data**

The purpose of this study is to determine if early data on outcomes following surgery can inform the design of future research studies. Two common types of outcomes following surgery are collecting electronic health data (e.g., medical records) and gathering data using apps on personal digital assistants and smartphones. Your participation is voluntary, and you can withdraw from the study at any time without penalty. The study is funded by the National Institutes of Health and the National Institute on Aging.

Outcomes Research, a non-profit, independent nonprofit organization in the United States, is coordinating this study. If you have any questions about the study, please contact the Study Coordinator or the Research Team Contact listed below.

The study involves collecting electronic health data (EHR) and patient-reported outcomes (PRO) from participants undergoing surgery. The data will be used to inform the design of future research studies.

**Principal Investigator:**

**Site Principal Investigator:**

**Research Team Contact:**

Insert the name and contact information of the research team member responsible for participant contact.

**Project Title:**

Feasibility pilot trial for the Trajectories of Recovery after Intravenous propofol versus inhaled Volatile anesthetic (THRIVE) Trial

**Research Team Contact:**

Insert the name and phone number of at least one research team member for participants to contact with questions, concerns, or issues.

Review the form before proceeding.

**Agree** if you are ready to continue.

Tasks:

- Mood and Affect
- Frailty Questionnaire
- Disability Assessment
- Quality of Recovery
MPOG Patient Matching App

MPOG Import Manager
Clinicians

Electronic Health Record
- Clinical data (diagnoses, surgical procedure details, lab values)
- Propofol TIVA vs Inhaled Volatile protocol adherence
- Safety outcomes

Patient Identifiers from MQUARK

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Sex</th>
<th>Date of Birth</th>
<th>MRN</th>
<th>Date of Surgery</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appleseed</td>
<td>Johnny</td>
<td>Male</td>
<td>1944-07-12</td>
<td>123456789</td>
<td>2021-10-12</td>
<td>Otolaryngology</td>
</tr>
</tbody>
</table>

Possible Matches from MPOG

<table>
<thead>
<tr>
<th>Exact Match</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appleseed</td>
</tr>
<tr>
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</tr>
<tr>
<td>2021-10-12</td>
</tr>
<tr>
<td>DIRECT LARYNGOSCOPY AND BRONC</td>
</tr>
</tbody>
</table>

THRIVE
Data Coordinating Center: Technical Support

<table>
<thead>
<tr>
<th>Technical</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ MPOG EHR interface active</td>
</tr>
<tr>
<td>☐ MPOG patient matching software loaded to system</td>
</tr>
<tr>
<td>☐ Access granted in MQUARK and MyDataHelps (see DOA for who requires access)</td>
</tr>
<tr>
<td>☐ Site number assigned</td>
</tr>
</tbody>
</table>
Data Coordinating Center: Technical Support

**Training**

- [ ] MyDataHelps training complete
- [x] MQUARK training complete (including name matching application)
- [ ] MOP and Protocol training complete
- [ ] Assessment training complete
- [ ] Relevant competency checklist passed by study team
Questions?

askthrive@umich.edu
Site Expectations

Bethany Pennington
Allison Janda
Overview Site Expectations

- Feasibility Protocol Overview
- Full Phase Overview
- Participation Considerations
Feasibility Phase
Projected Timeline

- **7/1/2022 – 6/30/2023**
  - Full Study Phase

- **7/1/2023**
  - Begin enrollment (first patient in)

- **8/1/2023**
  - Complete Patient Enrollment

- **6/30/2028**
  - Peer Review / Report Writing Period

- **7/1/2028 – 6/30/2029**
  - Full Study Phase End
Feasibility Study

300 Patients Across 2 Centers

PROPOFOL TIVA
Randomization of Patients Undergoing Surgery with General Anesthesia

INHALED VOLATILE

EFFECTIVENESS OUTCOMES AND BENEFITS
Quality of Recovery
Functional Status
Deltirum
Activity

Recovery After Surgery
Daily Wearable Signals

SAFETY OUTCOMES AND SIDE EFFECTS
Awareness with Recall
Kidney Injury
Respiratory Failure
Mortality

Measured between postoperative day 0 and 90
FEASIBILITY PILOT TRIAL: Primary Endpoints

**Prior to Surgery**

- **Screen** non-cardiac elective surgical patients
- **Approach** eligible patients before surgery
- **Consent** patients willing to participate

**Primary Endpoint 1:**
Proportion of patients who consent to participate in the study among those who are approached.

**DOS**

- 300 Randomized
- **150 Propofol TIVA**
  - **No** administration of Inhaled Agent
- **150 INVA**
  - **Must** administer Inhaled Agent

**Primary Endpoint 2:**
Proportion of patients in the propofol TIVA group and the INVA group who receive the assigned treatment.
**FEASIBILITY PILOT TRIAL: Secondary Endpoints**

**Data Collected**
- Frailty Assessment
- Quality of recovery
- Depression
- Functional Status
- Delirium
- Intraoperative Awareness
- Patient movement
- Kidney Injury
- Respiratory Failure
- Hypotension
- Mortality
- Other Adverse Events
- Fresh Gas Flows
- Inhaled Gas Concentrations
- IV Medication dosages
- Emergence Duration
- Daily Step Count
- Daily Stand Hours
- Sleep Monitoring

**Data Source (Database)**
- PRO (MyDataHelps)
- Clinician report & EHR (MPOG & MQUARK)
- FitBit or Apple Watch (MyDataHelps)

**Secondary Endpoints:**
- Proportion of data collection instruments and fields that are completed at each timepoint.
- Proportion of patients with complete EHR data.
- Proportion of patients with successful case linking.
- Proportion of enrolled patients with successful transfer of data into analytical case files.
- Proportion of safety & adverse events with accurate and complete documentation.
Goals

**Enroll enough patients**
> 10% of patients who are approached consent

**Administer the assigned anesthetic successfully**
> 80% compliance with each treatment allocation

**Complete data collection**
> 90% obtainment of complete data from EHR and questionnaires
Full Study Phase
Full Study Phase

12,500 Patients Across 20+ Centers

PROPOFOL TIVA
Randomization of Patients Undergoing Surgery with General Anesthesia

INHALED VOLATILE

EFFECTIVENESS OUTCOMES AND BENEFITS
- Functional Status
- Delirium
- Activity
- Daily Wearable Signals

QUALITY OF RECOVERY
- Measured between postoperative day 0 and 30

SAFETY OUTCOMES AND SIDE EFFECTS
- Recovery After Surgery
- Measured between postoperative day 0 and 90

- Mortality
- Respiratory Failure
- Kidney Injury
- Awareness with Recall
<table>
<thead>
<tr>
<th>Expected patient enrollment</th>
<th>Inclusion criteria*</th>
<th>Exclusion criteria#</th>
</tr>
</thead>
</table>
| 12,500 patients at 23 sites | 1. Aged 18 years or older  
2. Undergoing elective non-cardiac surgery expected to last ≥ 60 min requiring general anesthesia with a tracheal tube or laryngeal mask airway (or similar supra-glottic device) | 1. Inability to provide informed consent in English or Spanish  
2. Pregnancy (based on patient report or positive test on the day of surgery)  
3. Surgical procedure requiring general, regional, neuraxial anesthesia administered by an anesthesia clinician (anesthesiologist, CRNA, anesthesiology assistant) occurring within 30 days prior to or planned to occur within 30 days after surgery date  
4. Contraindication to propofol TIVA or inhaled volatile (for example, documented allergy to propofol, history of severe postoperative nausea or vomiting, concern for or history of malignant hyperthermia) based on self-report  
5. Surgical procedures requiring a specific general anesthesia technique (for example, TIVA required for neuromonitoring)  
6. Locally approved, written protocol mandating a particular anesthetic technique  
8. Planned postoperative intubation |
| ~544 patients enrolled/site over 5 years |  |  |
| ~109 patients/year |  |  |
| ~9 patients/month |  |  |
## Primary Objectives & Endpoints

<table>
<thead>
<tr>
<th>Primary Objectives</th>
<th>Endpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compare the early patient quality of recovery after anesthesia and surgery following TIVA with propofol and INVA.</td>
<td>Mean patient reported Quality of Recovery-15 (QOR15) score on POD1.</td>
</tr>
<tr>
<td>Determine whether intraoperative awareness is similarly uncommon with propofol TIVA and INVA.</td>
<td>Incidence of unintended intraoperative awareness with recall at either POD1 or POD30.</td>
</tr>
</tbody>
</table>
# Primary & Secondary Outcomes

<table>
<thead>
<tr>
<th>Type</th>
<th>Outcome</th>
<th>Specific measure or definition</th>
<th>Source or Data System</th>
<th>Timepoints</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Primary (effectiveness)</em></td>
<td>Quality of Recovery</td>
<td>Quality of Recovery 15 Instrument</td>
<td>Patient reported outcome</td>
<td>Day 1</td>
</tr>
<tr>
<td><em>Primary (safety)</em></td>
<td>Intraoperative Awareness</td>
<td>Modified Brice Interview</td>
<td>Interview or Patient reported outcome</td>
<td>Day 1 and/or 30</td>
</tr>
<tr>
<td>Secondary (effectiveness)</td>
<td>Delirium</td>
<td>UBCAM</td>
<td>Interview</td>
<td>Day 1</td>
</tr>
<tr>
<td>Secondary (effectiveness)</td>
<td>Quality of Recovery</td>
<td>Quality of Recovery 15 Instrument</td>
<td>Patient reported outcome</td>
<td>Day 0, 2, 7</td>
</tr>
<tr>
<td>Secondary (effectiveness)</td>
<td>Functional status</td>
<td>Change from preoperative baseline in World Health Organization Disability Assessment</td>
<td>Patient reported outcome</td>
<td>Day 30 &amp; 90</td>
</tr>
<tr>
<td>Secondary (safety)</td>
<td>Stage 1 Acute kidney injury</td>
<td>Creatinine increase of 50% or 0.3 mg/dl from preoperative baseline (KDIGO)</td>
<td>MPOG EHR interface</td>
<td>Day 7</td>
</tr>
<tr>
<td>Secondary (safety)</td>
<td>Respiratory failure</td>
<td>Reintubation within 6 hr or continued intubation 6 hr after surgery</td>
<td>Coordinator</td>
<td>Day 0</td>
</tr>
<tr>
<td>Secondary (safety)</td>
<td>Mortality</td>
<td>All-cause mortality</td>
<td>MPOG EHR interface &amp; NDIC</td>
<td>Day 30, 90</td>
</tr>
</tbody>
</table>
# Primary & Secondary Outcomes (Continued)

<table>
<thead>
<tr>
<th>Type</th>
<th>Outcome</th>
<th>Specific measure or definition</th>
<th>Source or Data System</th>
<th>Timepoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary (safety)</td>
<td>Intraoperative hypotension</td>
<td>Duration of mean arterial pressure &lt; 65 mmHg (minutes)</td>
<td>MPOG EHR interface</td>
<td>During surgery</td>
</tr>
<tr>
<td>Secondary (safety)</td>
<td>Intraoperative hypotension</td>
<td>Cumulative duration of mean arterial pressure &lt; 55 mmHg of 20 or more minutes</td>
<td>MPOG EHR interface</td>
<td>During surgery</td>
</tr>
<tr>
<td>Secondary (safety)</td>
<td>Intraoperative movement</td>
<td>Moderate to severe intraoperative movement reported</td>
<td>Clinician Report</td>
<td>During surgery</td>
</tr>
<tr>
<td>Secondary (safety)</td>
<td>Unplanned admission</td>
<td>Hospital admission no later than 24 hours after surgery performed at an ambulatory care center.</td>
<td>MPOG EHR interface</td>
<td>Day 0-1</td>
</tr>
<tr>
<td>Secondary (safety)</td>
<td>Propofol related infusion syndrome or Malignant hyperthermia</td>
<td>See full phase protocol</td>
<td>Clinician Report</td>
<td>During surgery</td>
</tr>
<tr>
<td>Secondary (effectiveness)</td>
<td>Daily step count, Daily stand hours, Total sleep time, sleep onset latency, wake after sleep onset, sleep efficiency, midpoint of sleep</td>
<td>Fitbit or Apple Watch</td>
<td>MyDataHelps</td>
<td>Day 7, 30</td>
</tr>
</tbody>
</table>

EHR = electronic health record
Recruitment, Screening, Enrollment

- Patient-facing website *(coming soon)*
- Multiple complementary enrollment strategies:
  - Individualized outreach to participants at home via telephone or email
  - In-clinic enrollment during preoperative assessment
  - Surgical patient community engagement
- Electronic Consent:
  - Patients will complete written informed consent via 1) study coordinator-mediated eConsent on a study tablet or computer; or 2) self-consent using modules on a personal smartphone, tablet, or website
- Subset of patients will be offered a study-provided wearable device (Apple Watch or Fitbit) or the option to use their own wearable device.
  - Participation in this aspect of the study is optional.
Protocol Adherence

*Administering the assigned method of anesthesia per protocol is essential for success*

Propofol TIVA:

- Administer IV propofol
- Do NOT administer inhaled anesthetics (sevoflurane, isoflurane, desflurane, nitrous oxide) during any part of the anesthetic care.

INVA:

- Administer inhaled volatile anesthetic (sevoflurane, isoflurane, desflurane) as the mainstay of anesthetic maintenance.
- Propofol is permitted for induction or as an adjunct.

*Patients in both groups may receive any additional IV adjuncts as deemed appropriate by the clinical team*
EEG Monitoring

- Each site will be expected to ensure EEG monitoring is consistent in both treatment arms
- Number of EEG monitors available
- Training study staff or clinicians setup process
- Clinician EEG Educational Resources Available on the MPOG website: https://mpog.org/thrive-clinician-educational-resources/
Blinding

- **Patients**
  - EPIC patient portal does not reveal intraoperative anesthesia details
  - Patients will be asked which intervention they believe they received at day 90 and will be informed of what they received

- **Study team**
  - Study personnel collecting and analyzing outcome data
  - Designated healthcare workers administering the post-Brice questionnaires
  - Intraoperative awareness classification team

- **Surgeons**
  - Email reminder
  - Pre-trial education

- **Postoperative nurses**
  - Signs in room
  - Pre-trial education
Participation Considerations
Research Coordinator & Site-PI

- Research Coordinator
  - Training
    - MQUARK, MyDataHelps, MPOG Patient Matching, UBCAM
    - Establish relationship with patients
    - OR familiarity and etiquette if new to this space
    - Setting up room, providing resources, collecting items after case
    - EEG setup
- Site-PI and THRIVE site clinicians
  - Available to provide hands-on support and education in OR
  - Troubleshooting issues that arise during the case
Intraoperative Awareness Protocol

● **Modified Brice Questions**
  ○ Released to the patient for self-administration on POD1
  ○ If Brice screen is positive, a THRIVE team member will be notified within 24 hours to perform the follow up questionnaire.

● **Follow up questionnaire**
  ○ THRIVE team member will perform an audio-recorded interview within 7 days of the + Brice
  ○ Offer to contact, or provide contact information for, a licensed psychologist or psychiatrist

  *This will be in accordance with the local process established for referring patients who experience intraoperative awareness for counseling at each participating institution*

● **Michigan Awareness Classification**
  ○ Three independent experts on awareness will listen to the audio-recording and adjudicate whether the awareness report was a definite awareness event, possible awareness event, or related to something else.
  ○ Apply the Michigan Awareness Classification
3 Data Platforms

Research Coordinators

Coordinator Entered Data
- Screening, approach, consent data
- Study workflow
- Randomization allocation
- Patient reported outcomes
- Follow up data

MQUARK

Patients

Participant Provided Information
- Digital copy of informed consent
- Baseline surveys
- Patient reported outcomes
- Wearable data

MyDataHelps

Clinicians

Electronic Health Record
- Clinical data (diagnoses, surgical procedure details)
- Propofol TIVA vs Inhaled Volatile protocol adherence
- Safety outcomes

MPOG Import Manager

THRIEVER Central Database

Data Quality Diagnostics  Trial Operational Metrics  Analytical Dataset
MQUARK

- MQUARK (MPOG Quality and Research Kit) will be used to manage patient screening, enrollment and randomization eCRFs

- This existing research system has been customized to the needs of the THRIVE trial and provides integration with data collected from the other systems

- Patient enrollment details, patient demographics, per protocol treatment delivered and clinician report of intraoperative patient movement, SAEs, and AEs will be entered into MQUARK
MyDataHelps

- MyDataHelps is a patient-facing application that allows the collection of patient reported outcome data via the administration of surveys

- Surveys can be completed by dedicated smartphone application, email or web

- Additionally, data will be obtained from wearable devices (Apple Watch or Google FitBit or compatible “bring your own device [BYOD]”) using the MyDataHelps application
MPOG & THRIVE

- THRIVE is embedded within MPOG
- At U-M there is a parallel, trial specific infrastructure for handling THRIVE patients
- THRIVE study data is uploaded and processed separately from existing MPOG processes
- New tool: **MPOG Patient Matching Application**
  - Joins MPOG Record to Trial Data
  - Handles uploads of THRIVE study data
MPOG - Data Quality Matters

- THRIVE is an EHR (MPOG) embedded clinical trial
  - Active MPOG participation is required for THRIVE participation
  - At a site the THRIVE and MPOG teams work collaboratively for effective participation

- Emphasis on Data Quality Control:
  - Site activation activities - Checking mappings, data diagnostics, case level validation
  - Ongoing site maintenance - Data Diagnostics, Case Validation, Reports from DCC etc
  - Specific to THRIVE, but familiar from MPOG tools.

- Things will happen… planning is key:
  - New monitors, anesthesia machines, EHRs etc will all potentially impact THRIVE participation
  - DCC will be partner in planning for these
Site Activation Checklist

- Summarizes actions sites need to complete before approval to start study enrollment and study procedures
  - Technical (MPOG, MQUARK, MyData Helps)
  - Clinical (Education, Stakeholder outreach, EEG)
  - Administrative (Subcontracts, staff)
  - Training (study personnel, competency checklist)
  - Plan Development (Recruitment, Stakeholders)
  - Regulatory (IRB, Delegation of Authority)
  - Process Overview (payment, wearables)
Questions?
Lessons Learned in Feasibility

University of Michigan
Washington University St. Louis
10/21/2022
Allison Janda
Sathish Kumar
Laura Swisher
Before Beginning Recruitment and Enrollment

Plan enough lead time to accomplish:

- **Clinician Education and Study Information**
  - CRNAs, Nurses, Clinicians, Surgeons
  - Grand Rounds
  - Present study at clinician regular weekly meetings
  - THRIVE Developed Slide Decks can be made available

- **Single IRB Application (sIRB)**
  - Submission to WUSTL sIRB successful
  - ~8 weeks
  - Reliance agreement
  - Allows for differences between institutions

- **MPOG Interface Status**
  - Complete any Outstanding issues with MPOG data transfer and/or contracting
Before Beginning Recruitment and Enrollment cont.

Equipment and Pharmaceutical needs

- Make sure you have an adequate number of infusion channels available
- Ensure necessary medications & equipment readily available regardless of study arm
- Familiarize CRCs and engaged clinicians with the use of Epic secure chat or some other group messaging system (Teams, Slack, etc) to potentially help with surgery team communication day of surgery
- Site co-Is need to be available to discuss any concerns the surgery team may have related to existing protocols (e.g. opioid avoidance when randomized to TIVA)
Before Beginning Recruitment and Enrollment cont.

EEG Considerations

- Inventory of available EEG monitors, confirm adequate for study use
- Training coordinators for use and troubleshooting of EEG monitoring devices
- Ensure data from EEG monitors is captured
- Spare leads, cables.
- Education – providers in the room, coordinators, preop and post nursing teams
Before Beginning Recruitment and Enrollment cont.

● Create an EPIC search tool that accurately reflects inclusion/exclusion criteria and become familiar with where the criteria can be found within Epic
  ○ Real time surgery start and stop times, Surgery complexity, Family history

● Establish recruitment strategy that fits your team
  ○ Assign blinded versus unblinded CRCs
  ○ Assign CRCs to recruit based on day of surgery to control surgery/day volume

● Ramp Up
  ○ Consider only recruiting patients with surgeries that occur Monday - Wednesday, no first starts, and only inpatient surgeries in the first week or two
Study Start-up Timeline: Washington University School of Medicine

Education and Dissemination of the Study Begins

- Anesthesiology Grand Rounds, Presentations to CRNAs, Nurses, Techs, Emails to Surgeons

July 13th, 2022

Single IRB (sIRB) WUSTL Application Submitted

July 17th

sIRB Application Approved

August 1st

Staff Onboarding Begins

- MQUARK and MyDataHelps training, MOP and protocol training, EPIC training, Workflow Creation

August 22nd

First Patient Randomized

August 29th

First Patient Enrolled

September 6th
Study Start-up Timeline: University of Michigan

- June 3rd, 2022: Additional SEoLINES ordered
- July 5th: Single IRB (sIRB) Application submitted to WUSTL
- July 13th: Education and Dissemination of the Study Begins
- August 2nd: Single IRB (sIRB) Application Approved
- August 8th: Staff Onboarding Begins
- August 10th: U of M Site IRB approved
- Sept. 9th: First Patient Randomized
- Sept. 8th: U of M Site IRB submitted
- Sept. 12th: U of M Site IRB approved
- Sept. 9th: First Patient Enrolled
- August 10th: Single IRB (sIRB) Application Approved by WUSTL

- Additional SEoLINES ordered
- Anesthesiology Grand Rounds, Presentations to CRNAs, Residents, Nurses, Techs, Emails to Surgeons
- MQUARK and MyDataHelps training, MOP and protocol training, EPIC training, Workflow Creation
Recruitment and Enrollment

- Appropriate Surgical Site, Procedure and Supportive Surgical Team
- Helps Ascertain Workflow and understand nuances
- Screening Tools (more diligent screening in the initial period)
- Email, Follow up Calls, Set limits on follow up Calls
- Check for overlapping research studies
Day of Surgery and Postoperative Period

- Randomize after all checks including survey, communication to the team to prepare for the type of anesthetic
- **Avoid unblinding the patient and the coordinator involved in survey postop**
- Continually checking the EHR to monitor completion of surgery
  - Tracking surgery for early start times/end times
  - Asking a clinician to page you when patient enters phase 2
Patient may be very groggy or nauseated when waking up which may delay administering/directing completion of POD 0 surveys and evaluations.

- If patient is not able to answer the POD 0 surveys this may mean they are CAM+ and the rest of the questionnaires may be skipped

UBCAM cannot be completed over the phone which may impact outpatients

**TAKE AWAY LESSONS**

- Timing of performing surveys
- Collecting the checklist at the end of the case/including feedback
After POD 0

- Continuous checking to make sure all surveys are complete
- Do not be afraid to reach out to patients to ask them to complete surveys throughout the 90 days of study involvement
Dashboard Status

**Potential Patients**: 38

**Approached**: 69

**Enrolled**: 27

**Screening Complete**: 43

**Withdrawn**: 2

**2 Days Preop**: 0

**1 Day Preop**: 0

**7 Days Preop**: 0

**Patients who Need Surveys Administered**: 0

**Patients with Past Due Surveys**: 0

**Check for SAEs**: 0
# Enrollment and Randomization as of October 20th, 2022

<table>
<thead>
<tr>
<th></th>
<th>University of Michigan</th>
<th>WUSTL</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approached (bidirectional)</td>
<td>43</td>
<td>52</td>
<td>95</td>
</tr>
<tr>
<td>Enrolled</td>
<td>28</td>
<td>46</td>
<td>74</td>
</tr>
<tr>
<td>Ratio of consented versus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>approached</td>
<td>65%</td>
<td>88%</td>
<td>78%</td>
</tr>
<tr>
<td>Withdrawn before randomization</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Withdrawn after randomization</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Randomized</td>
<td>19</td>
<td>28</td>
<td>47</td>
</tr>
<tr>
<td>Protocol adherence*</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

*“Protocol adherence” defined by clinician self-report and coordinator manual review. Detailed MPOG EHR phenotypes may change this percentage.*
Summary

- Overall a Very Positive Experience
- **Certainly A Feasible Study**
- Our Experience and Learning Opportunities would help prepare for the full phase study
- Will continue to Share our Experience to future sites
- Teamwork, Communication and Collaboration is Key
- Surgeon and Anesthesiology team feedback
Contracting & Financials
Contracting

- University of Michigan is prime awardee for THRIVE
- All site enrollment contracts will occur through University of Michigan
- Builds upon existing MPOG site contracts
- Single contract that includes
  - Statement of work
  - Financial terms
  - Data use agreement language
  - Confidentiality, IP
  - All PCORI THRIVE contract obligations and language
- Contracts can be signed, but not “active” until full scale approved by PCORI
Financials

- Budget reviewed extensively with PCORI prior to Feasibility Phase
- Goal is to maximize $ allocated to enrollment sites while staying within PCORI PLACER limits
- 56% of all funds flow to enrollment sites

- Initial financial model built upon 12 enrollment sites
- Remains stable, with some CC adjustments, at 20+ sites

- PCORI indirect limit of 40%
Reimbursement model

- Per patient randomized
- Between $950 - $1000 per patient
- Inclusive of indirect costs
- Participant receives additional up to $75 incentive
- Lump sum start-up payment upon first patient randomized
Reimbursement model

- Additional non-participant reimbursement
- Annual incentives for excellent performance
  - Representative population demographics
  - Pace of enrollment
  - Intervention adherence
- Small grant program for stakeholder engagement activities
Questions & feedback
• In PCORI-funded research, patients and other healthcare stakeholders are equitable partners—as opposed to research subjects—who leverage their lived experience and expertise to influence research to be more patient centered, relevant, and useful.

• *Engagement* is the meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the entire research process—from planning the study, to conducting the study, and disseminating study results.

https://www.pcori.org/engagement/value-engagement
Patient And Family Engagement: A Framework For Understanding The Elements And Developing Interventions And Policies
Engagement in THRIVE

• Proposal development
• Feasibility phase
  • Patient engagement
  • Internal stakeholder engagement
  • External stakeholder engagement
• Plans for full study phase
Patient Partners During Proposal Prep

- Reviewed potential outcome measures and helped select QOR15 as primary outcome
- Successfully advocated for choice of awareness with recall as primary safety outcome
- Participated in determining meaningful effect size for awareness power calculation
Patient partner Donna Penner has had several surgeries with general anesthesia, including an abdominal surgery with inhaled volatile anesthesia during which she experienced prolonged and distressing intraoperative awareness. Penner states, “The THRIVE research project that we are conducting is compelling, especially when you include the part about how devastating it is to experience awareness... and how it impacts us in our daily living. It cost me my career... I’ll take a few sleepless nights any day to prevent someone from going through what I’ve been through. Any day. In a heartbeat.”

Patient partner Linda Robison has had several surgeries with general anesthesia, including spine surgery with propofol TIVA 11 years ago. Robison states, “As an intraoperative awareness victim, being invited to participate in THRIVE is profoundly meaningful. With my continued struggle with PTSD caused by the event, I am hopeful my input will be of value and used in the prevention of awareness. This opportunity will allow me to be heard globally by medical professionals and aid in my healing. I dedicate my participation to all those victims who’ve gone before me and suffered in silence.”

Sara Solomon, a patient partner in THRIVE who has had general anesthesia three times in the last 15 years, states, “If I had a choice of general anesthesia that improved recovery but with a small risk of waking up during surgery, I don’t think I’d take it. From what I hear, that’s traumatic, and I’d like to keep my love affair with anesthesia alive! If, however, I could choose a type of anesthesia that improved my chance of a faster and higher quality recovery, I’d take it.”
THRIVE Revised Engagement Plan

1. To establish mechanisms and resources for patient and stakeholder input and consultation on key study decisions over the lifespan of THRIVE;

2. To demonstrate feasibility of patient and stakeholder collaboration and shared leadership within the central management structure of the THRIVE trial;

3. To generate and curate resources and tools to support meaningful patient and stakeholder engagement at the level of individual THRIVE recruiting sites;

4. To complete necessary staff training and other preparatory work at the level of individual recruiting sites to support successful site-level patient and stakeholder engagement within the THRIVE full study phase.
Patient Partner Panel

 THRIVE Patient Partner - Past Anesthesia Experience (N=17)

- 1 = positive/good
- 2 = negative/bad
- 3 = both positive/good and negative/bad

 THRIVE Patient Partner Time Since Last Receiving Anesthesia (N=17)

- Between 11-19 years ago: 1
- Between 1-5 years ago: 7
- Within the year: 9
Patient Partner Panel – Monthly Meetings

Structured agenda:

• **Learning to THRIVE** – educational offering
• Presentation related to agenda theme
• Bi-directional discussion/feedback/deliverables for the meeting

**Learning to THRIVE**

May
What is a Clinical Trial? – NIH Module

June
What is Informed Consent? NIH Module

August
Intro to PCORI Approach to Patient Centered Outcomes Research – PCORI Research Fundamentals

Sept
Sampling, Recruiting & Retaining Study Participants – PCORI Research Fundamentals
Patient Engagement Working Group

• Alignment of leadership & facilitation for both patient engagement groups – Mark Neuman, Hugo Campos & Mara Bollini

• Provides operational oversight of patient and caregiver engagement activities within THRIVE

• Manages relationships with patient partners and ensures integration of patient and caregiver voice throughout the study

• Oversees patient & caregiver engagement measures of success

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Location</th>
<th>Organization</th>
<th>Role</th>
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</thead>
<tbody>
<tr>
<td>Avidan</td>
<td>Michael</td>
<td>Missouri</td>
<td>WU</td>
<td>Co-Principal Investigator</td>
</tr>
<tr>
<td>Bollini</td>
<td>Mara</td>
<td>Missouri</td>
<td>WU</td>
<td>Program Mgr/Staff</td>
</tr>
<tr>
<td>Campos</td>
<td>Hugo</td>
<td>California</td>
<td>Unaffiliated</td>
<td>Patient Partner</td>
</tr>
<tr>
<td>Carron</td>
<td>Jen</td>
<td>Missouri</td>
<td>BJC/WU</td>
<td>Patient Experience/Staff</td>
</tr>
<tr>
<td>Chu</td>
<td>Larry</td>
<td>California</td>
<td>Stanford</td>
<td>Co-Investigator</td>
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<tr>
<td>Eyrich</td>
<td>Nicole</td>
<td>Michigan</td>
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<td>Program Mgr/Staff</td>
</tr>
<tr>
<td>Kheterpal</td>
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<td>U of Michigan</td>
<td>Co-Principal Investigator</td>
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<tr>
<td>Neuman</td>
<td>Mark</td>
<td>Pennsylvania</td>
<td>UPENN</td>
<td>Co-Investigator/Site PI</td>
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<tr>
<td>Pennington</td>
<td>Bethany</td>
<td>Missouri</td>
<td>WU</td>
<td>Co-Investigator</td>
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<tr>
<td>Price</td>
<td>Amy</td>
<td>Florida</td>
<td>Stanford</td>
<td>Co-Investigator</td>
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<tr>
<td>Swisher</td>
<td>Laura</td>
<td>Missouri</td>
<td>WU</td>
<td>Program Mgr/Staff</td>
</tr>
</tbody>
</table>
Internal Stakeholder Activities

Clinician Education and Intervention Adherence Working Group:

- Anesthesia Clinician Education
  - Grand Rounds presentation
  - Website created with educational videos, tips and resources: [https://mpog.org/thrive-clinician-educational-resources/](https://mpog.org/thrive-clinician-educational-resources/)
  - One-on-one clinician education and support during the THRIVE feasibility study

- Quarterly Clinician newsletter
Internal Stakeholder Activities (continued)

- **Non-anesthesia Clinician/Perioperative Education**
  - Personalized THRIVE study overview, FAQs and defined roles presented at multidisciplinary group meetings in August 2022:
    - Surgeons
    - Perioperative nursing
    - Anesthesia Technicians

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**FAQs For Surgical Colleagues**

**Why are we performing this trial?**
- To find out which is better: total intravenous anesthesia (TIVA) or inhaled anesthesia
  - Inhaled anesthesia and TIVA have been used safely and interchangeably for decades, but we don’t know which leads to improved quality of recovery for surgical patients. To answer this foundational question, we have received $30 million from PCORI.

**What are the interventions?**
- TIVA or inhaled anesthesia
  - Patients will be randomized to receive one of these.

**What are the outcomes?**
- Quality of recovery on day 1 and intraoperative awareness
  - Secondary outcomes include delirium, disability, respiratory failure, acute kidney injury, postoperative activity and sleep, and all-cause mortality. Intraoperative patient movement and delayed emergence will also be assessed.

**How do the results of this trial impact you?**

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**THRIVE**

**Trajectories of Recovery after Intravenous Propofol vs inhaled VolatileE anesthesia**

- THRIVE is a multicenter RCT evaluating whether propofol TIVA or inhaled volatile anesthesia results in better patient experiences.
- With $30 million in funding from PCORI and enrolling 12,500 patients, THRIVE is one of the largest perioperative clinical trials to date.
- THRIVE is led by investigators at the University of Michigan and Washington University in St. Louis.

**Eligibility:**
- Adults undergoing elective non-cardiac surgeries ≥ 60 minutes requiring general anesthesia with a tracheal tube or supraglottic airway (e.g. LMA)

**FEASIBILITY PHASE: 7/1/2022 – 6/30/2023**
- Before initiating the full scale study, we must prove that it is possible to conduct this trial.
- 300 patients from the University of Michigan and Washington University St. Louis will be enrolled.
- Our primary aim in the feasibility phase include:
External Advisory Board

- Payer, Public health, National Specialty Organizations, Community groups
Stakeholder Experience

• THRIVE should ensure that all stakeholders have a *positive experience*
• Ensure **ALL** voices are heard
  • *Patient Partners*
    • Ongoing education throughout the trial
    • Opportunities to extend their role into other working groups, expanding projects related to THRIVE
    • Re-assessment of needs, interest, experience and opportunity to provide feedback
  • *Internal Stakeholders*
    • Clinician support and education throughout the trial
    • Ongoing communication and follow up
    • Thank you cards and tokens of appreciation
  • *External Advisory Board*
Engagement goals: site activities

• Overall
  • Completion of selected PCORI-developed training in partnered research principles over the course of the study
  • Interval “engagement rounds discussions” on investigator calls
  • https://research-teams.pcori.org/engaging-stakeholders

• Internal stakeholder engagement: integrated into startup/launch process
  • Onboarding/orientation of local clinical teams
  • Establishment of buy-in from institutional leaders
  • Feedback on study processes from local stakeholders
  • Collection of surgeon satisfaction/operating conditions info
Engagement goals: site activities

- **Patient engagement**
  - Goal to conduct 6-12 focus groups over the course of the study to represent site-level patient voices
  - Goal for each site to identify 2-4 patient participants, plus PI and lead coordinator
    - Individuals who have completed THRIVE and agreed to be contacted for additional projects
    - Other local patient partners (e.g., patient/family advisory board members)
  - Focus groups to be organized centrally by Wash U, UM, or Penn teams

- **Patient/external stakeholder engagement**
  - All sites invited to submit proposals for additional engagement activities focused on patients or external local stakeholder groups (e.g., churches, government, community groups)
  - THRIVE team will fund approved engagement activities at site level up to $5,000/site
Discussion
REGAIN: Top 5 Lessons Learned for THRIVE

Mark D. Neuman, MD, MSc
University of Pennsylvania
Pragmatic RCT of spinal versus general anesthesia for hip fracture surgery

Enrollment (targeted & actual): 1,600 patients enrolled 2/2016-2/2021
- 22,022 patients screened!

46 centers in US & Canada

Primary outcome: recovery of independence in walking at 60 days after randomization

Funding: Patient Centered Outcomes Research Institute, $11.8M/5Y
1. It’s accrual world out there
REGAIN FINAL COUNTS BY SITE (PATIENTS RANDOMIZED)
2. Time is the enemy
# Time to selected IRB approval milestones via central vs local IRB review for initial site approval for 34 REGAIN trial sites approved before May 1, 2017

<table>
<thead>
<tr>
<th>Time in days from receipt of IRB materials to local IRB submission (median, IQR)</th>
<th>Central review (N=9)</th>
<th>Local review (N=25)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>39 (35, 134)</td>
<td>58 (41, 105)</td>
<td>0.711</td>
<td></td>
</tr>
<tr>
<td>Time in days from local IRB submission to final IRB approval (median, IQR)</td>
<td>27 (14, 32)</td>
<td>66 (29, 138)</td>
<td>0.026</td>
</tr>
<tr>
<td>Time in days from receipt of IRB materials to final IRB approval (median, IQR)</td>
<td>100 (71, 148)</td>
<td>132 (87, 209)</td>
<td>0.191</td>
</tr>
</tbody>
</table>
3. Anesthesia practice is chaotic
Case study: Site 431

- **PID 4310028**: Anesthesia team unable to place spinal after multiple attempts by 2 providers; patient received general anesthesia.
- **PID 4310029**: Patient requested general anesthesia while being positioned for spinal. Patient received general anesthesia
- **PID 4310036**: Patient began vomiting after arrival in the operating room. Anesthesia provider opted for general anesthesia due to potential aspiration risk with sedation.
Managing crossovers: distinguishing “clinical” from “logistical” events

- Site detailing & coaching to minimize logistical crossovers
- Site-level troubleshooting for issues with provider performance
- 1 site suspended for non-adherence (6 crossovers RA→GA w/in 1st 20 patients randomized)

<table>
<thead>
<tr>
<th>Reason for crossover</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal attempted, unable to place</td>
<td>52 (43.7)</td>
</tr>
<tr>
<td>Clinician selected general anesthesia</td>
<td>29 (24.4)</td>
</tr>
<tr>
<td>Patient/proxy request</td>
<td>18 (15.1)</td>
</tr>
<tr>
<td>Block failure or intraoperative event necessitating conversion to GA</td>
<td>12 (10.1)</td>
</tr>
<tr>
<td>Miscommunication/scheduling</td>
<td>7 (5.9)</td>
</tr>
<tr>
<td>No reason</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Total</td>
<td>119 (100)</td>
</tr>
</tbody>
</table>
4. Docs gonna doc
Well, I mean there I think the patient 100 percent takes precedence....So I’m sorry I’m breaking your – I’m basically going to the other arm and basically breaking protocol. But I strongly believe that this is the best for my patient right now. So I will do this regardless of whether they’ve been involved in the study or not. –REGAIN Clinician
5. Every successful trial represents the solution to its own specific collective action problem
Spinal Anesthesia or General Anesthesia for Hip Surgery in Older Adults


Annals of Internal Medicine

Pain, Analgesic Use, and Patient Satisfaction With Spinal versus General Anesthesia for Hip Fracture Surgery

A Randomized Clinical Trial

Mark D. Neuman, MD, MSc; Rui Feng, PhD; Susan S. Ellenberg, PhD; Frederick Sieber, MD; Daniel I. Sessler, MD; Jay Magaziner, PhD, MS/Phg; Nabil Elkassabany, MD; Eric S. Schwenk, MD; Derek Dillane, MD; Edward R. Marcantonio, MD, MSc; Diane Menio, MS; Sabry Ayad, MD; Manal Hassan, MD; Trevor Stone, MD; Steven Papp, MD; Derek Donegan, MD; Mitchell Marshall, MD; J. Douglas Jaffe, DO; Charles Luke, MD; Balkam Sharma, MD; Syed Azim, MD; Robert Hymes, MD; Ki-Jin Chin, MD; Richard Sheppard, MD; Barry Perlman, PhD, MD; Joshua Sappenfield, MD; Ellen Hauck, DO, PhD; Mark A. Hoeft, MD; Ann Tierney, MS; Lakisha J. Gaskins, MPH; Annamarie D. Horan, MPA, PhD; Trina Brown; James Dattilo, BS; Jeffrey L. Carson, MD; on behalf of the REGAIN (Regional versus General Anesthesia for Promoting Independence after Hip Fracture) Investigators®
Co-Investigators & Partners
- Susan Ellenberg
- Rui Feng
- Jeffrey Carson
- Frederick Sieber
- Jay Magaziner
- Diane Menio
- Stephen Kates
- Edward Marcantonio
- Nabil Elkassabany
- Samir Mehta
- Lee Fleisher
- Sandy Schwartz
- Denise Orwig
- Jennifer Hruslinski
- Greg O’Neill
- Christine Langlois
- Alisa Stevens-Shields

Site Investigators
- Trevor Stone
- M. Kwesie Kwofie
- Yatish Ranganath
- Kamen Vlassakov
- Dan Sessler

REGAIN DSMB
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- Stephen Choi
- Ki Jinn Chin
- David Sanders
- Steven Papp
- Robert Hymes

REGAIN Staff
- Lakisha Gaskins
- Jim Datillo
- Ann Tierney
- Trina Brown
- Janice Ashton
- Brittany Montgomery
- Annamarie Horan
- Samuel Oduwole
- Tom Rose
- Brandon Eilberg
- Maithri Goud
- Peter Preston
- Cassandra Dinh

Funders
- The Patient–Centered Outcomes Research Institute
- The National Institute on Aging
- The Foundation for Anesthesia Education and Research
- University of Pennsylvania Department of Anesthesiology & Critical Care

THANK YOU!!!
Next Steps
Thank You!

Reception Rex Terrace, 9th Floor JW Marriot Hotel