



JOHNS HOPKINS

INSTITUTE *for* CLINICAL &
TRANSLATIONAL RESEARCH

Trial Advisor Program (TAP)

Nichol McBee, MPH, ACRP-CP

Faculty Lead, TAP and Executive Director BIOS Clinical Trials Coordinating Center

March 21, 2024

TAP Leadership - Johns Hopkins University

ICTR

- Daniel E. Ford, MD, MPH
 - *Director, Johns Hopkins Institute for Clinical and Translational Research (ICTR)*
 - *David M Levine Professor of Medicine*
- Charles Flexner, MD
 - *Chief Scientific Officer for Strategy and Integration*
- Craig Hendrix, MD
 - *Deputy Director, Translational Sciences Core*
- Liz Martinez, RN, BSN, CCRC
 - *Advocate Senior Clinical/Research Liaison*

BIOS

- Daniel F. Hanley, MD
 - *Director, BIOS Clinical Trials Coordinating Center*
 - *ICTR Deputy Director for Support & Innovation in Multi Center Trials, Principal Investigator*
- Karen Lane
 - *Deputy Director, BIOS Clinical Trials Coordinating Center*
 - *Trial Coordination*
- Nichol McBee
 - *Executive Director, BIOS Clinical Trials Coordinating Center*
 - *Data Coordination and Quality*
- Angeline Nanni & Jessica Baird
 - *Consult Navigators*

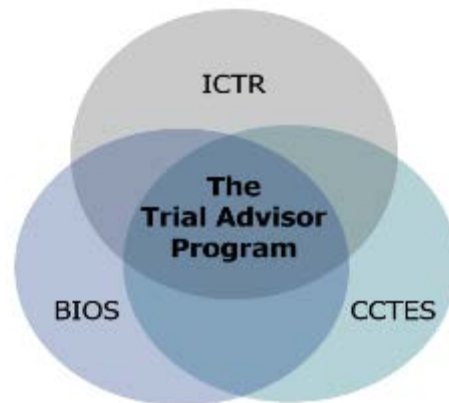
CCTES

- Douglas Jabs, MD, MBA
 - *Director, Center for Clinical Trials and Evidence Synthesis*
- Amy Zemanick
 - *Research Program Manger*

Overview of the ICTR Trial Advisor Program (TAP)

Composed of 3 key organizational partners

ICTR, BIOS, a JHU-based academic research organization, and
Center for Clinical Trials and Evidence Synthesis (CCTES)



- The TAP is committed to facilitating the development of investigative expertise and invite all investigators, including K-grant, T-grant, and other early career investigators, to participate.
- The TAP works with trials funded by the NIH, commercial sponsors, foundations, and other.

Purpose of the TAP

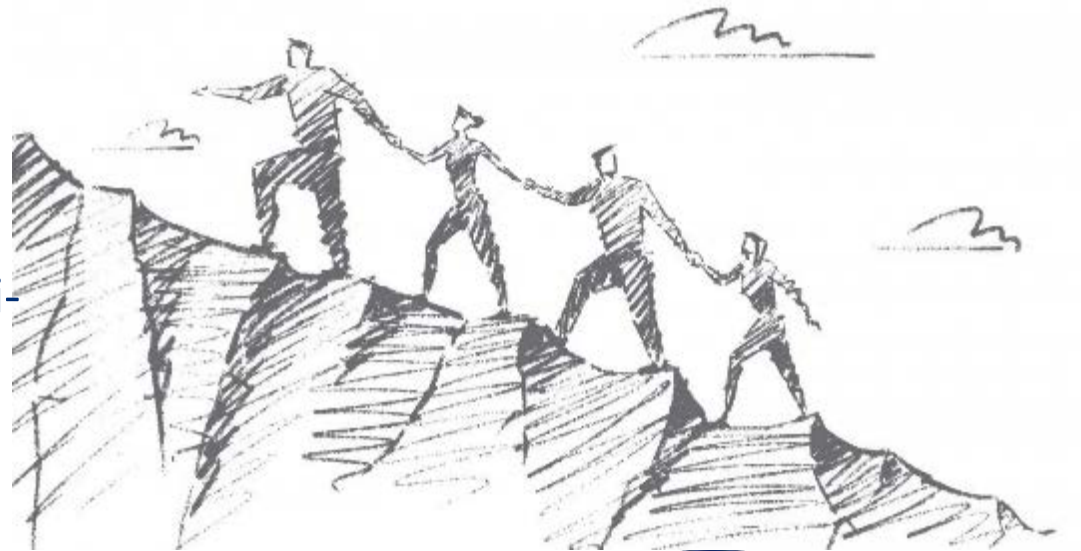
To support and advise all JHMI Principal Investigators in all departments, in all disease areas in their clinical trial pursuits



Working with the TAP

The TAP provides expert consultative support to investigators with small, local multi-center translational studies needing to:

1. **Improve** research study design, trial operations, and analysis plans
2. **Explore** opportunities for single and multi-center trial innovation
3. **Commit** to diversity and community engagement in clinical trials
4. **Assess** translational pathway and readiness for multi-center trials
5. **Provide** strategic assistance with grant applications
6. **Develop** and improve the overall stewardship, efficiency, accountability, and transparency of clinical trials.



TAP Strategies

- ➔ Develop a portal for local investigative teams to access trial development resources available within the CTSA
- ➔ Formalize the strategic organization of trial planning by integrating team's study development with the appropriate CTSA cores and CRUs
- ➔ Provide learning and mentoring opportunities for young investigators (K and T awardees)
- ➔ Develop relationships with University of Maryland, Kaiser Permanente, and Morgan State University to expand research opportunities
- ➔ Collect TAP metrics to gauge program success

Requests/Resources

Requests

- Study Design
- Study Budget
- Projected Timelines
- Recruitment Feasibility Assessment
- Study Feasibility
- Comparative Effectiveness

Resources

- Single IRB
- Standard Agreements
- Recruitment and Retention Plan
- Community Engagement Studio
- EHR-Based Cohort Assessment
 - PCORNet, TriNetX

Addressing Barriers to Clinical Research within the Trial Advisor Program

BARRIERS

Flawed design
Inefficient conduct

Lack of stakeholder engagement
Eligibility criteria too burdensome

Start-up delays,
e.g. IRB review,
contract execution

Fragmented operating models
Infrastructure rebuilt

Recruitment challenges
Long timelines,
altered study designs

High costs of data collection & management
Inadequate data collection & management

TAP OPPORTUNITIES

Consultations
with **local** clinical trial, disease, statistical, and recruitment experts

Specialized support from the **Recruitment Innovation Unit**

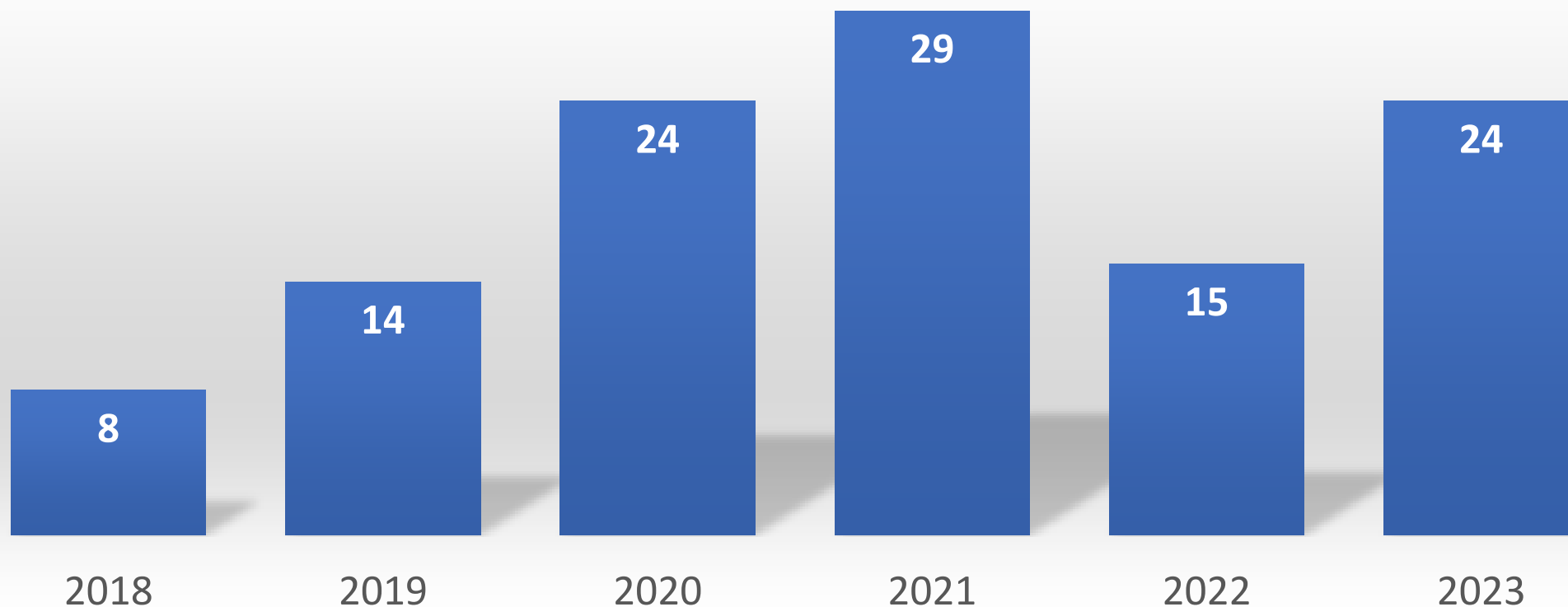
JHM Single IRB coordination, **Standard Agreement** toolkits

Referral to ICTR resources/cores for Clinical Coordinating Center, Data Coordinating Center, and Recruitment/Retention Planning depending on investigator needs (see ICTR website)

Johns Hopkins/Maryland ICTR TAP Consultations

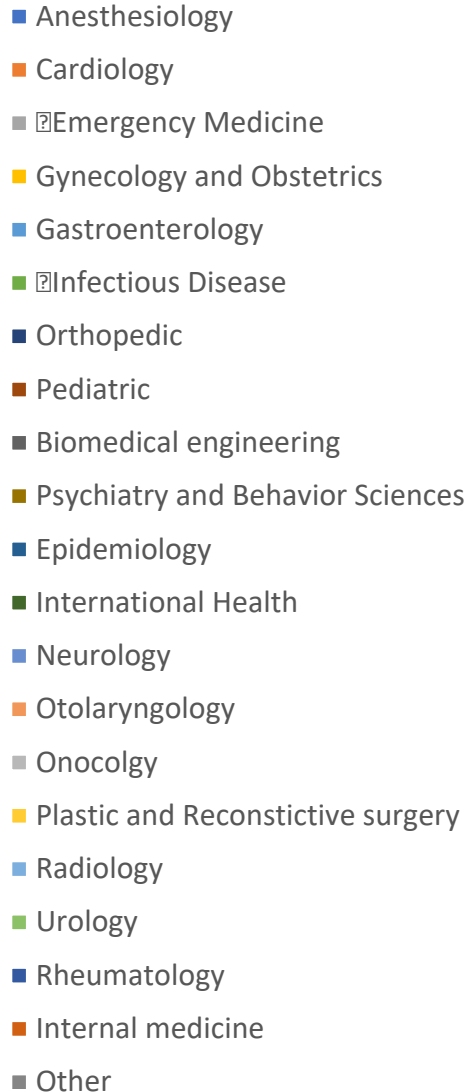
114 Consultations Requested of the TAP from 2018 to 2023

Trial Advisor Program Consults by Year 2018-2023



Data downloaded
3/17/2024

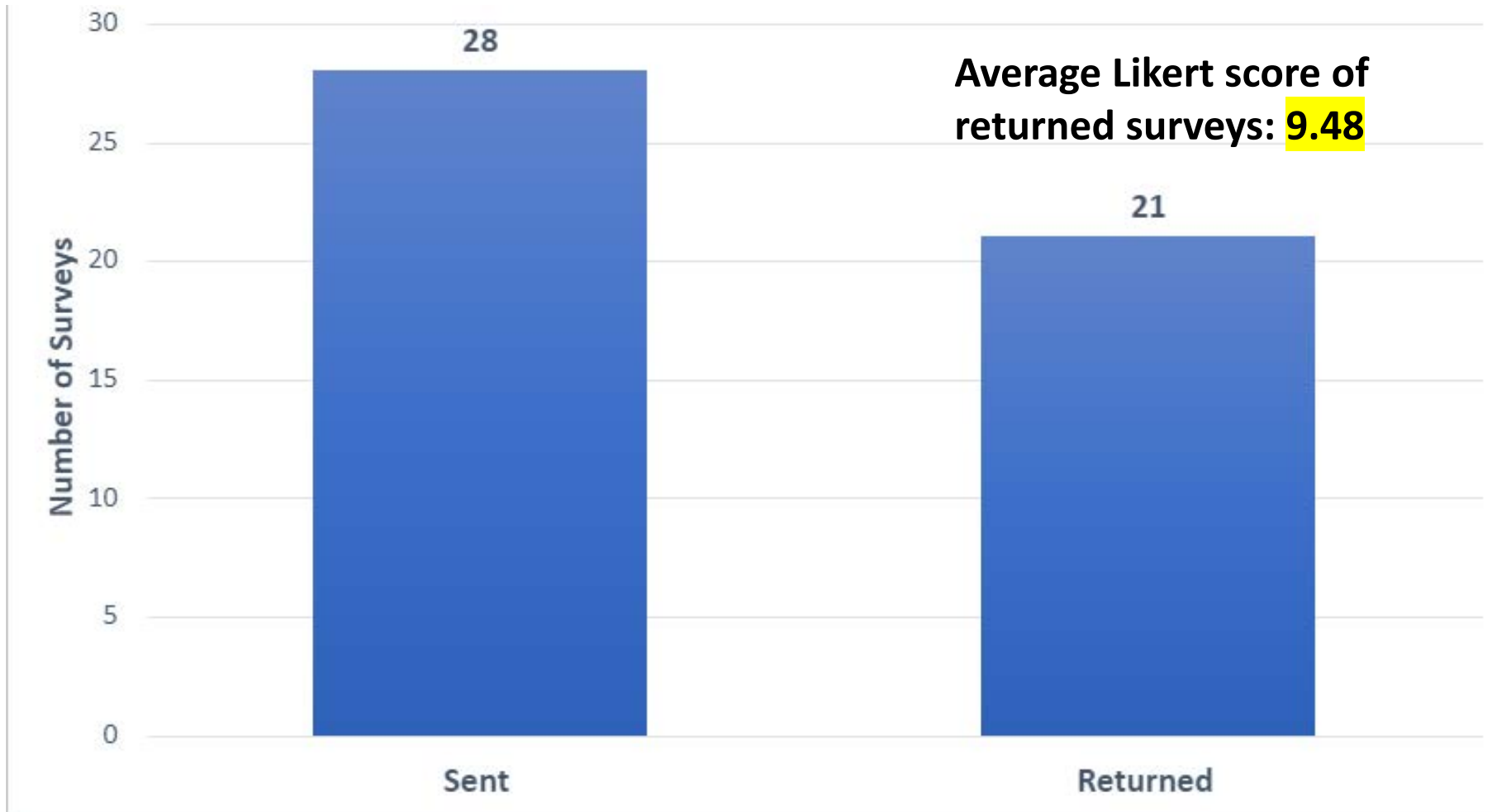
TAP Proposals by Therapeutic Areas



TAP largest # of consults

1. Neurology
2. Psychiatry and Behavior Sciences
3. Gastroenterology

TAP Satisfaction Surveys May 2021 to December 2023



TAP initial consultation satisfaction surveys began May 2021.

Data downloaded
2/23/2024

TAP Triage for JHU Investigators

Request a TAP consult via the ICTR website



5 business days to schedule an initial consult



Initial consult is a **1 to 2-hour meeting with content appropriate experts**

Follow-up meetings may occur; consultation will be completed within 30-60 days



TAP results could include



TAP Comprehensive Consultation

Referred to utilize BIOS infrastructure will evaluate potential collaboration and a shared funding application

Referral to ICTR Studio

A master class to help investigators improve the quality and impact of their research

Referral to specific ICTR cores

Referral to locally support specific proposal needs (fee and non-fee based support)

Referral to TIN for consultation

Referral to nationally support specific proposal needs

No further support

Initial Consultation satisfies all needs; no further support is requested/needed

In conclusion...Contact us: TAPTeam@jhu.edu

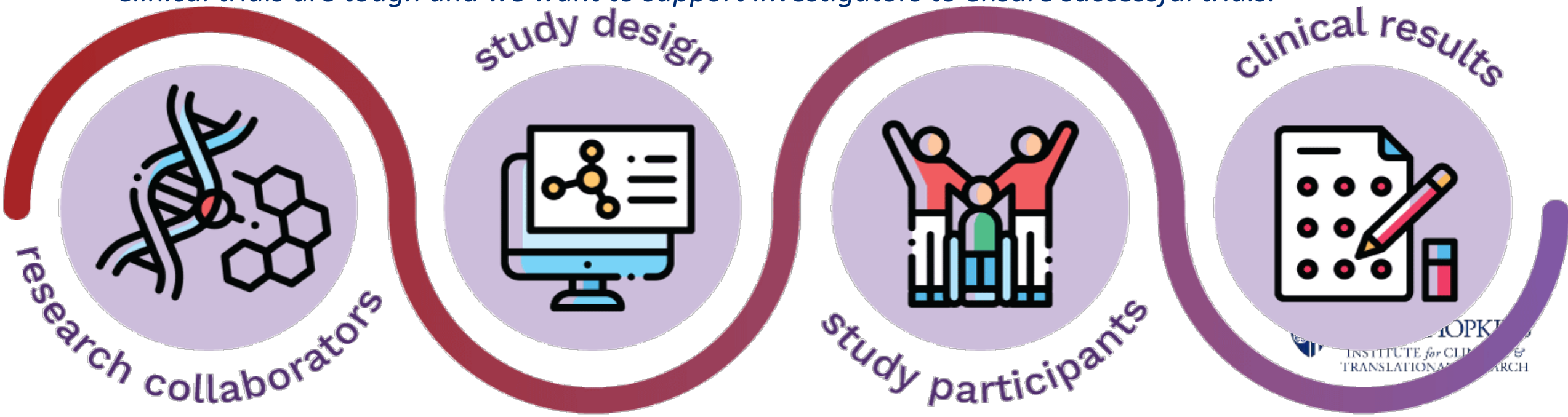
- It Takes a Village!

- Services are at 'no cost ' to Hopkins Investigators
- Consider applying or referring investigators to request a TAP consult

- Team approach to success!

- TAP (and ICTR) Goal:

"Clinical trials are tough and we want to support investigators to ensure successful trials."



How to Apply to the TAP

HOME > SERVICES AND RESOURCES > STUDY PLANNING RESOURCES > TRIAL ADVISOR PROGRAM (TAP)

“*The Trial Advisor Program (TAP), formerly known as the Trial Innovation Unit (TIU), is a service powered by the ICTR, the **BIOS CTCC** and the **CCTES**.***”**

Make a Request

Quick Links

- [BIOS Clinical Trial Coordinating Center](#)
- [Center for Clinical Trials and Evidence Synthesis](#)

Attend the next *Third Thursdays with the ICTR* March 21 at 2:00 pm to learn more about TAP! Register.

Press here to apply to the TAP

Please use the QR Code to Complete the survey





Thank you!

<https://ictr.johnshopkins.edu/service/study-planning/trial-advisor-program-tap/>