

OG | OneGI

SECOND ANNUAL  
GI & LIVER

*Summit*



# Clinical Research Update

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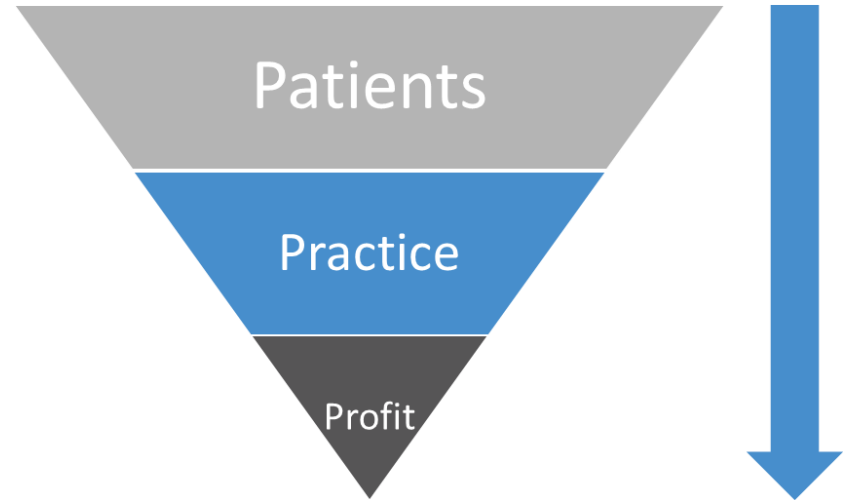


# Value of Clinical Research



**GOAL:** to allow practicing physicians to integrate quality clinical research into the practice as a sustainable ancillary service

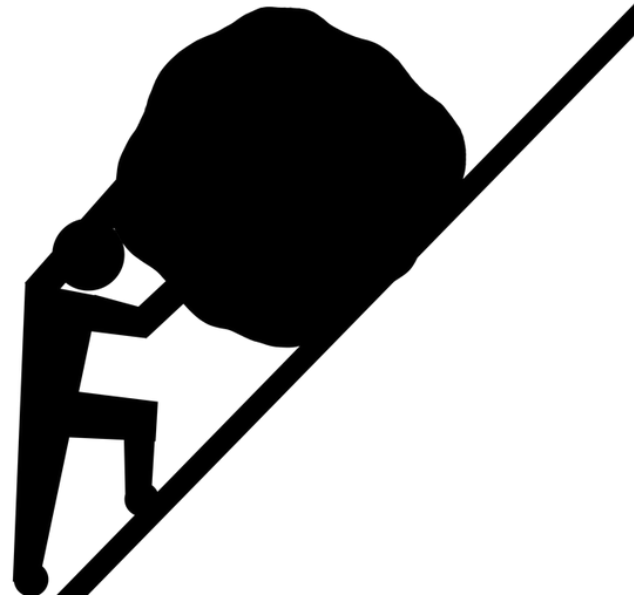
- **Patient**
  - Access to latest therapeutics
  - Closer follow-up
  - Ideal for patients with insurance issues
  - Option for tough cases
- **Practice**
  - Direct Value
  - Indirect Value
- **Profit**
  - Ancillary profit center
  - Feeds other aspects of the practice



# Challenges of Research in Practice



- **Infrastructure**
  - Building a sustainable program
  - Access to sponsors/ studies
  - Technology
  - Equipment
  - Personnel
  - Expertise in research
  - Assessing organizational health
- **Clinic**
  - Busy practice (time)
  - Lack of partner buy-in
  - Lack of referrals
- **Profit**
  - Budget effectiveness
  - Distribution of profits



# Clinical Research Study Types



- Interventional studies: can be phase 1–4
- Device/diagnostic studies
- Clinical registry studies
- Most of our studies will be phase 2–3  
randomized studies and “collection studies”

# Types of Research Staff



- Research assistants
- Research coordinators
- Research Nurses
- Regulatory coordinators
- Site managers
- Project managers
- Education/training/compliance
- Business manager
- Financial/controllers

# Research Divisions



- Luminal studies: mostly IBD but can also at times include reflux, eosinophilic esophagitis, gastroparesis etc
- Liver studies: mostly NASH and NASH cirrhosis but also PBC and PSC
- Collections studies: colorectal DNA, Hepatocellular cancer

# One GI Research Shared Services



- Contracting and budgeting
- Help with finding and contracting with vendors
- Regulatory
- Research EMR (real time CTMS)
- Training staff
- Soon: remote data entry and possibly remote coordinators with chart reviews



# One GI Research Sites



- Sites with longstanding clinical research: Gastro One, Dayton, GHP, CSLC/Ameritus (Lansdowne VA), Tidewater (Virginia Beach)
- Sites with new research centers: GANM (Oxford), DHS (Tupelo), Skyline (Jackson), GHS (Canton), DDC (Cleveland)- at this time only collection studies but starting interventional trials very soon
- Sites with clinical research outside of the One GI Research: Great Lakes Gastro (Ohio), AIG (Nashville), Gastroenterology Associates (Gainsville VA)

# APP Role/Help



- Keep a look out for enrolling studies
- Potential for participating in the research office as a sub-investigators: roles include performing physicals, reviewing research patient visits and ensuring protocol is followed, review inclusions/exclusions, review and assess adverse events, review labs and assess clinical significance, offer medical help for coordinators

# Example of One GI Trials



- Roche Genentech: simple collection study – 1075 patients enrolled as of Monday September 25
- DUET UC-CD studies
- Mirikizumab and BMS UC study
- Madrigal phase 3 program