

# Session VII – TME Diagnostics – Moderation: Munir Ghesani



March 23, 2024 | SAT | 15:30 – 16:20

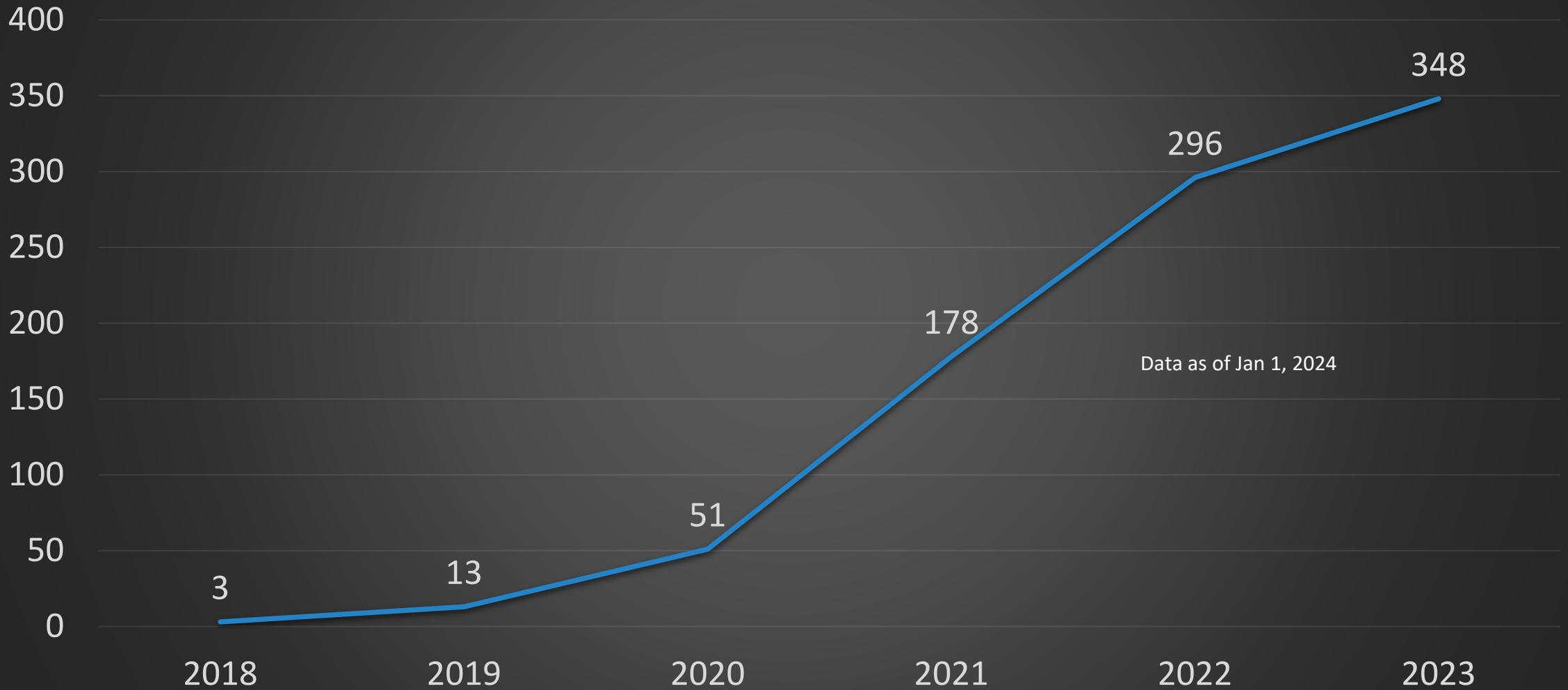
Introduction: Odile Jaume, CEO ICPO Foundation

March 22-24, 2024  
**7<sup>th</sup> Theranostics World Congress**  
Santiago, Chile

HOME INFORMATION PROGRAM REGISTRATION ABSTRACTS

- **Pieter van der Veken** (University of Antwerp, Belgium) DRUGLIKE, 18F-LABELED PET TRACERS TARGETING FIBROBLAST ACTIVATION PROTEIN (FAP)
- **Frederik Giesel** (Heinrich Heine University Düsseldorf, Germany) virtual OVERVIEW OF TODAY'S CLINICAL APPLICATIONS AND PERSPECTIVES
- **Sherly Mosessian** (Sofie Bioscience, USA) & Paul Evans (GE, USA) FAPI – ADVANCEMENTS IN DIAGNOSTICS
- **Tadashi Watabe** (Osaka University, Japan) – FAPI DIAGNOSTICS – CRITICAL VIEW ON CLINICAL DEVELOPMENT)

# Publications on FAP and PET imaging



# ClinicalTrials.gov

Find Studies ▾

Study Basics ▾

Submit Studies ▾

Data and API ▾

Policy ▾

About ▾

## Focus Your Search (all filters optional)

Condition/disease ⓘ

Other terms ⓘ

Intervention/treatment ⓘ

Location

Search by address, city, state, or country and select from the dropdown list

Search

**Search for:**

FAP

FAPI

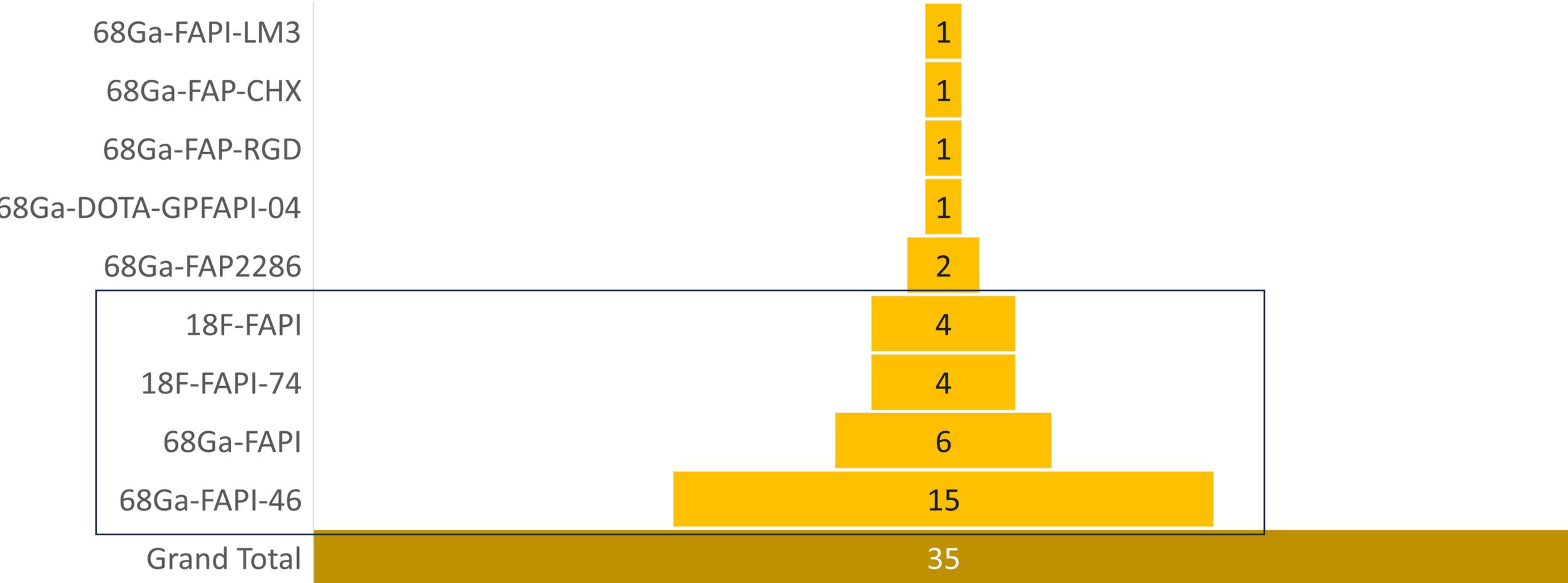
Fibroblast Activation Protein

**Filter for Diagnostic use only**

*Search conducted on March 4, 2024*

# FAPI tracers comprise the largest number of clinical studies

# of Studies



# Growth in FAP diagnostic clinical trials

## FAP Targeting-Clinical Trial Status

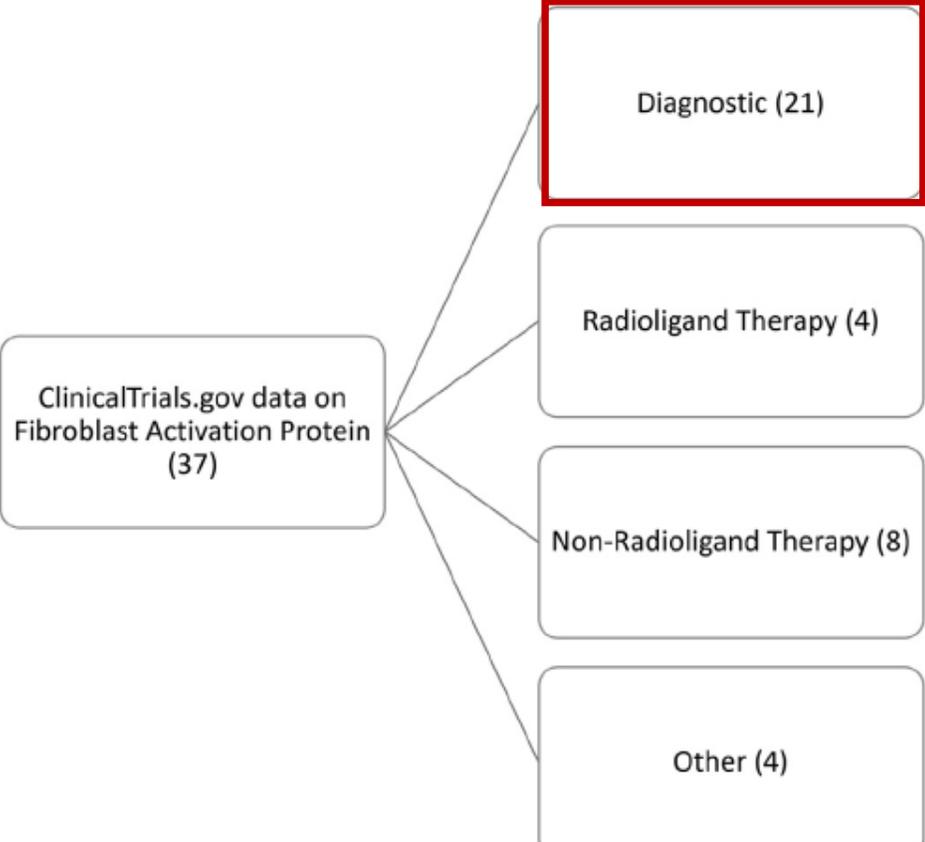
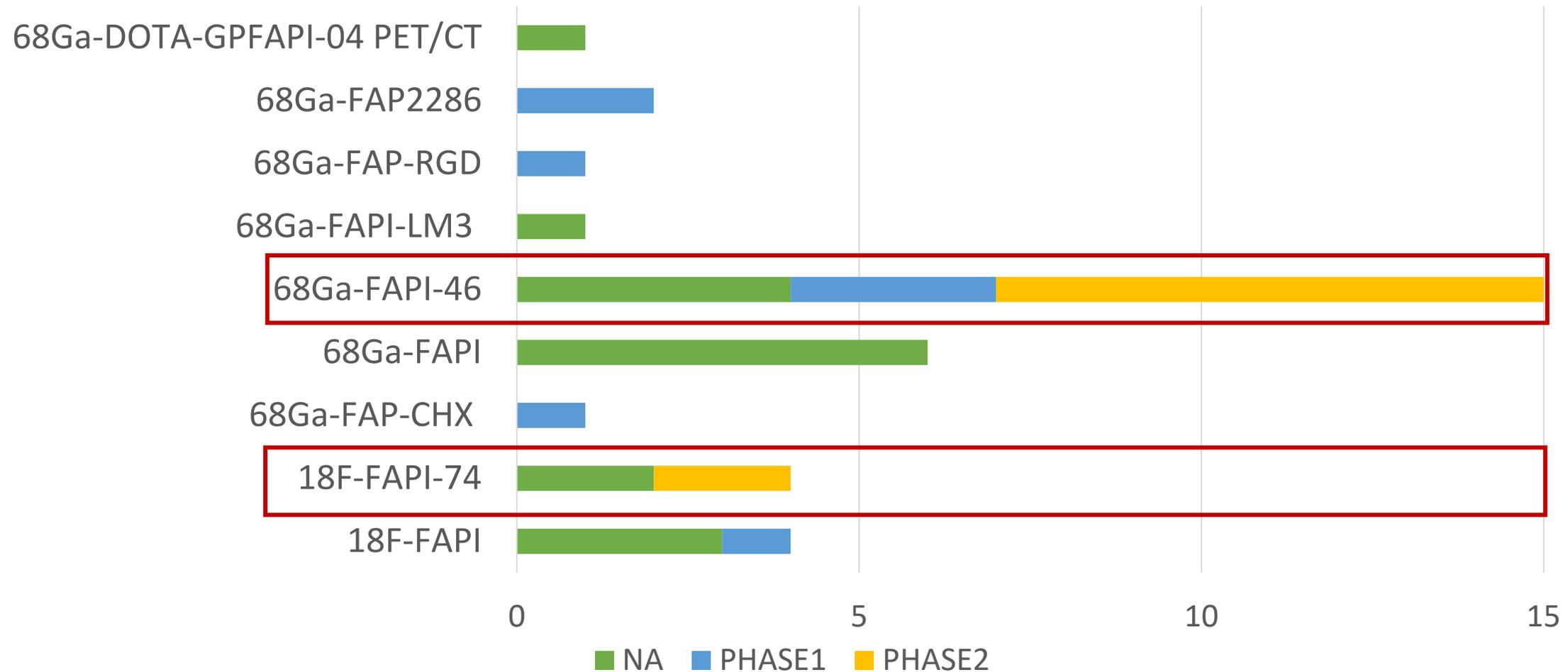


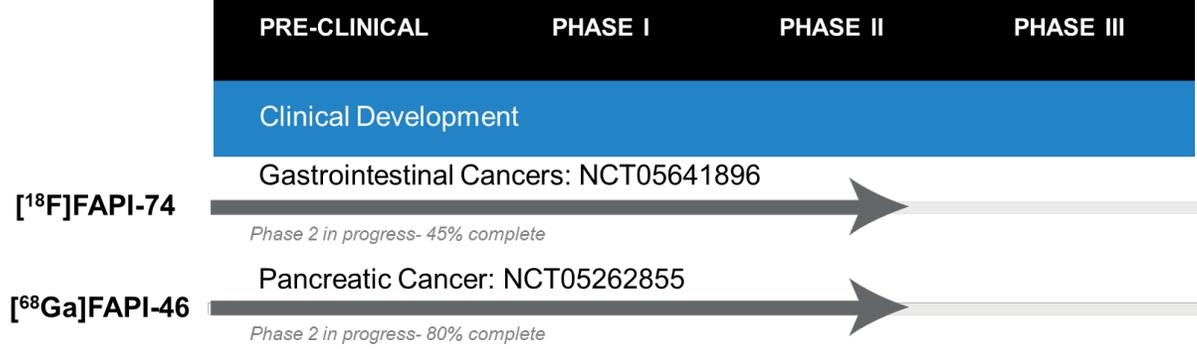
Fig. 1. ClinicalTrials.gov search results. Search results with keywords “FAP” and “Fibroblast Activation Protein” resulted in 37 studies. Further classification of the results broke down the data into 21 diagnostic studies with PET or PET/CT, four studies in radioligand therapy, eight therapeutic studies in non-radioligand therapy, followed by four studies under “Other.” The other studies included three completed genetic studies and one biologic intervention study currently active.

Data as of November 2022

# The most advanced tracers: [<sup>68</sup>Ga]FAPI-46 and [<sup>18</sup>F]FAPI-74

## Clinical Phases of FAP diagnostics





## [<sup>68</sup>Ga]FAPI-46

## [<sup>18</sup>F]FAPI-74

<ul style="list-style-type: none"> <li>Phase 2 in patients with Pancreatic Ductal Adenocarcinoma (PDAC)</li> </ul>		<ul style="list-style-type: none"> <li>Phase 2 in patients with GI Cancers: hepatocellular carcinoma, gastric cancer, colorectal and pancreatic cancer</li> </ul>
<p>4 sites activated: (Study activated May 2022)</p> <ul style="list-style-type: none"> <li><b>NYU Langone</b></li> <li><b>Mayo Clinic</b></li> <li><b>UCLA</b></li> <li><b>BAMF Health</b></li> </ul>		<p>5 sites selected: (Study activated May 2023)</p> <ul style="list-style-type: none"> <li><b>MGH</b></li> <li><b>MSKCC</b></li> <li><b>BAMF</b></li> <li><b>Northwell</b></li> <li>UCLA: Pending activation end of April 2024</li> </ul>
<p>68 Minutes</p>		<p>110 Minutes</p>
<p>60 subjects planned</p> <ul style="list-style-type: none"> <li>50 patients imaged (minimum one FAPI image)</li> </ul>		<p>80 subjects planned</p> <ul style="list-style-type: none"> <li>35 patients imaged</li> </ul>

# FAP Diagnostic

Stand-alone diagnostic

Companion diagnostic

Oncology

Non-oncology

RLT

Non-RLT

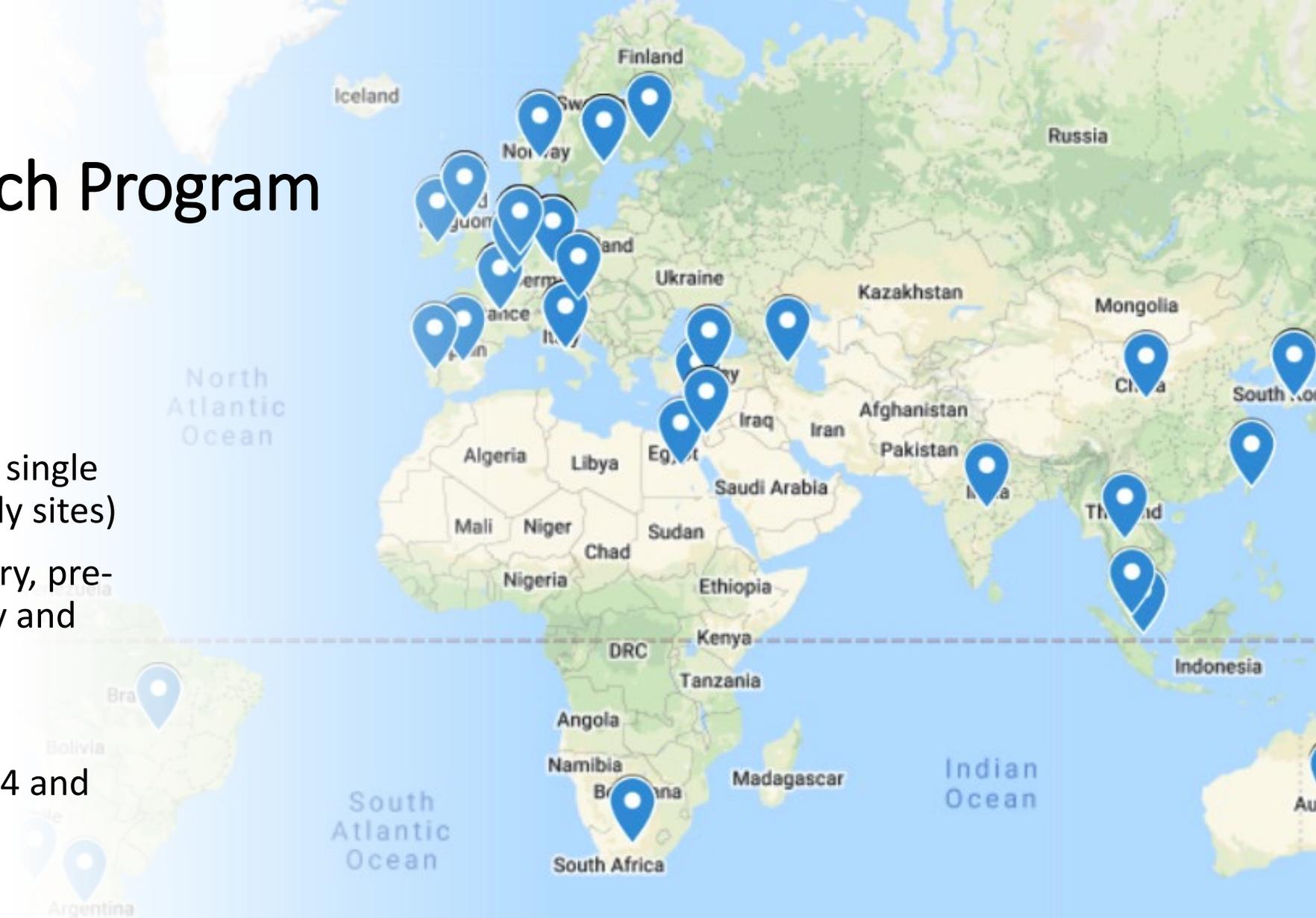
Oncology

Oncology

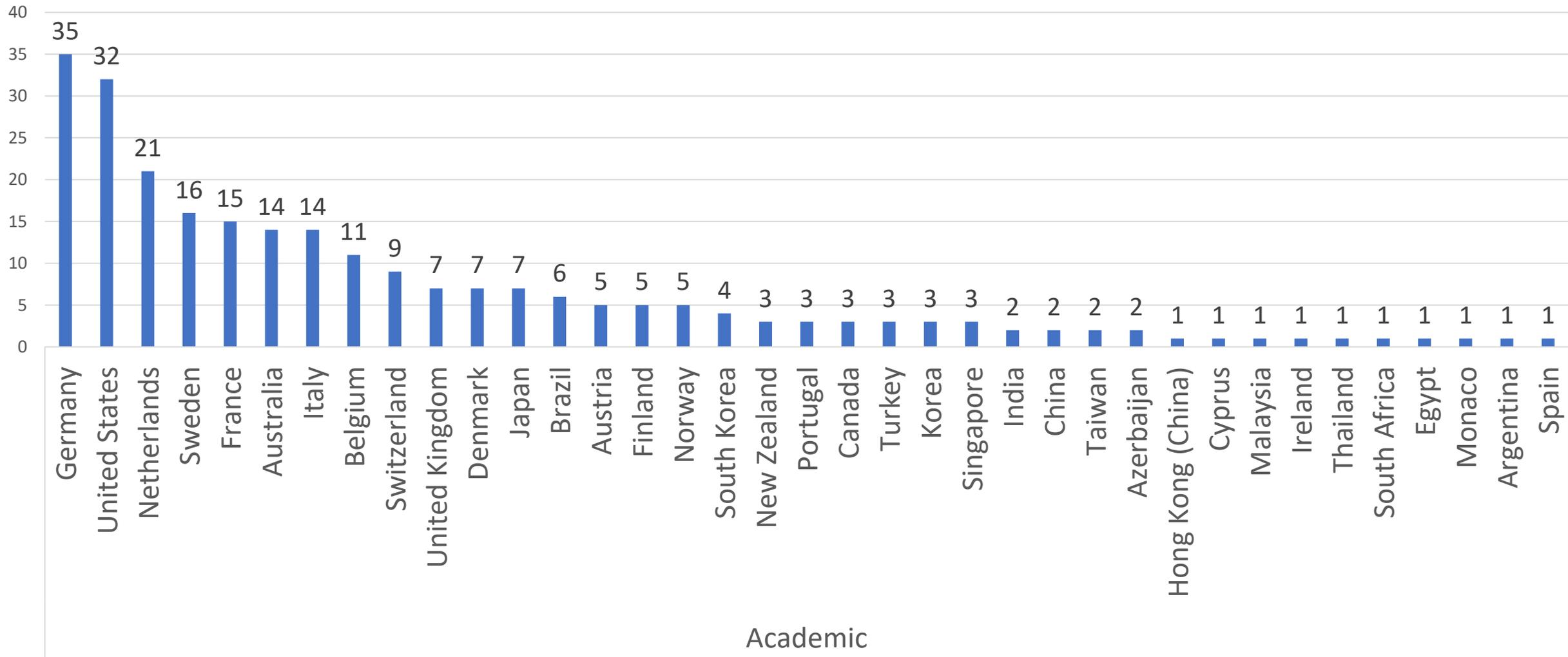
Non-oncology

# FAPI Global Outreach Program Current State

- 39 Countries
- 265 research studies (80 single study sites, 62 multi study sites)
- Studies include: Chemistry, pre-clinical, clinical, oncology and non-oncology
- 150 unique institutions
- Compounds: [ $^{18}\text{F}$ ]-FAPI-74 and [ $^{68}\text{Ga}$ ]-FAPI-46

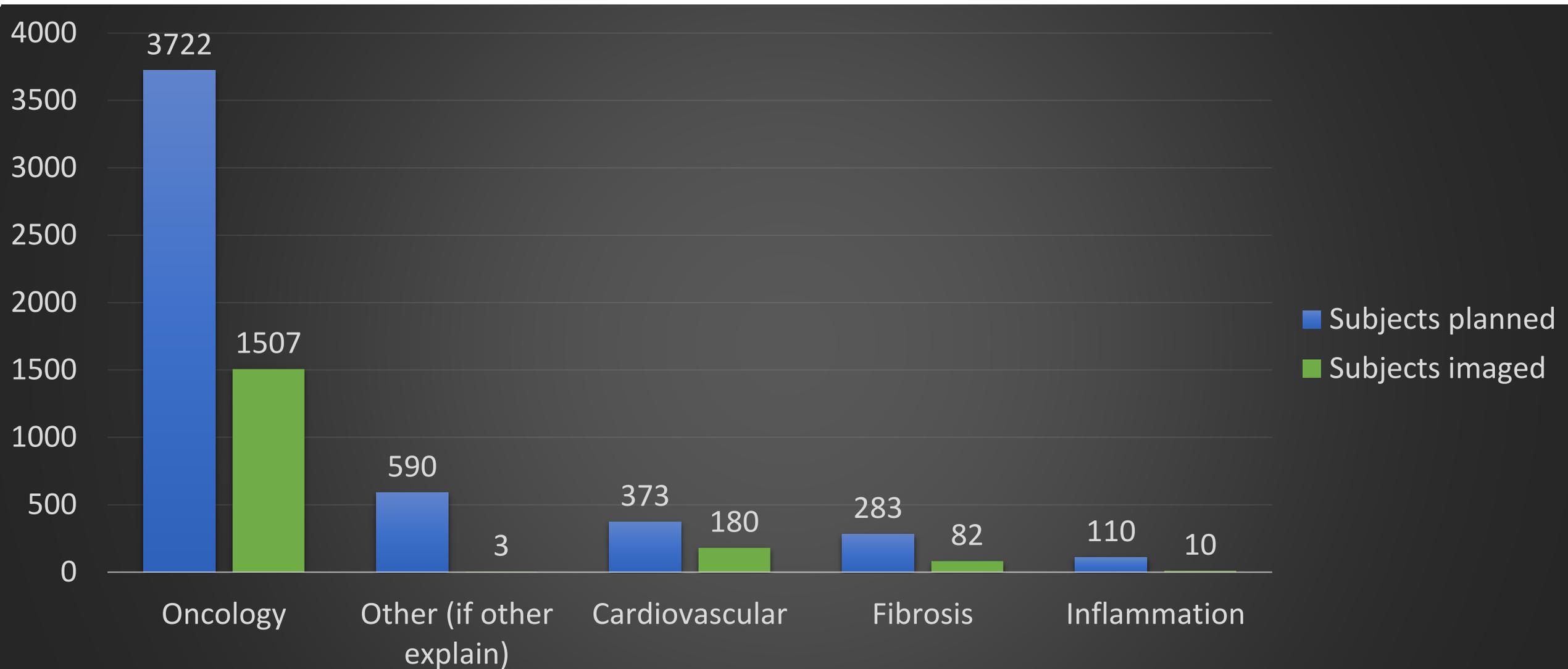


# Country breakdown of academic studies



**5078** subjects planned

**1782** subjects imaged



# Why FAPI Global Outreach Program?

## Primary Objective:

1. **Access:** Provide academic institutions access to FAPI for investigator-initiated studies to advance their and SOFIE/GEHC's research interests.
2. **Learn:** For SOFIE/GEHC to learn through this program the utility of FAPI in various indications.
3. **Data:** Identify key partners/data in support of approvals in key indications.

## What we do:

Gain access to GMP grade precursor and reference standard in support of investigator-initiated trial

Technical manufacturing assistance to get the sites started

Cross Reference to SOFIE/GEHC IND(s) or IND content to pursue investigator-initiated trial

Allows sites to expand their research program and grant opportunities

# Expansion of FAPI manufacturing across SOFIE Radiopharmacy Network



## Our Pipeline

With over 50 years of passion and dedication for the future of PET, we have taken bold steps to advance the development of next generation radiopharmaceuticals.

[VIEW PIPELINE](#)



## Partnership

We offer a range of contract manufacturing services to meet your clinical needs through our network and new Theranostics Center of Excellence.

[VIEW SERVICES](#)



## PET Education

We have created a multifaceted approach designed to strengthen the quality of PET programs in your practice and deliver enhanced care to your patients.

[LEARN MORE](#)



## Our Network

We have 14 network sites committed to on-time delivery of radiopharmaceuticals to meet our clients' need in diagnosing and treating critical illnesses every day.

[FIND A PHARMACY](#)

## Active

Totowa, NJ

Gilroy, CA (End of April 2024)

## Upcoming 2024 and 2025

Sanford, FL

Cleveland, OH

Romeoville, IL

Dallas, TX