

ICPO Theranostics FAP Summit  
Targeting the Tumor Microenvironment and Beyond  
Friday 4 & Saturday 5 November 2022



# FAPI Clinical Development Updates

Sherly Mosessian Ph.D.  
Chief Scientific Officer, SOFIE

11/5/22

# ICPO Theranostics FAP Summit

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**I have the following potential Conflict(s) of Interest to report:**

I serve as the Chief Scientific Officer for SOFIE

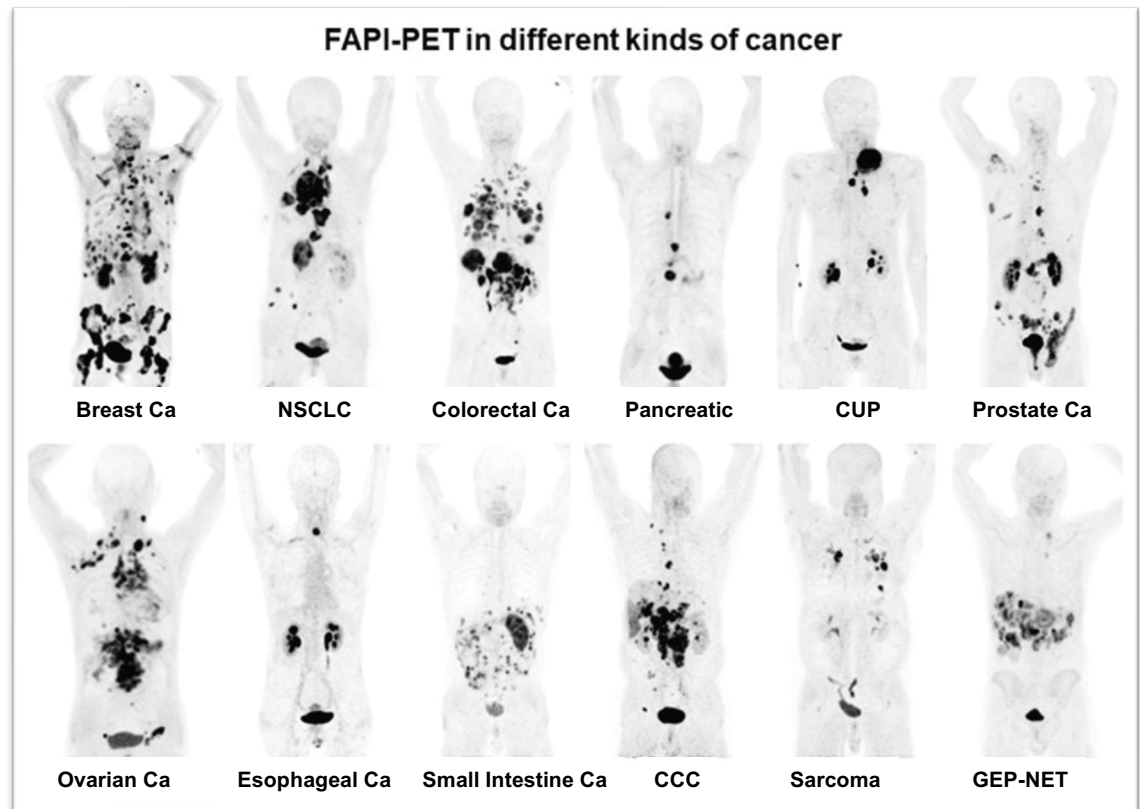
SOFIE has global commercial rights for diagnostic use of FAPI family of compounds from Heidelberg University

No conflicts to report

# FAP as a target for radiopharmaceuticals

## SNMMI Image of the Year 2019

“A single radiotracer can identify nearly 30 types of cancer, allowing for new applications in noninvasive diagnosis, staging and treatment, according to research presented at the 2019 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI). This honor goes to a team of researchers at University Hospital Heidelberg, Germany, showcasing the efficacy of the FAPI radiotracer.”

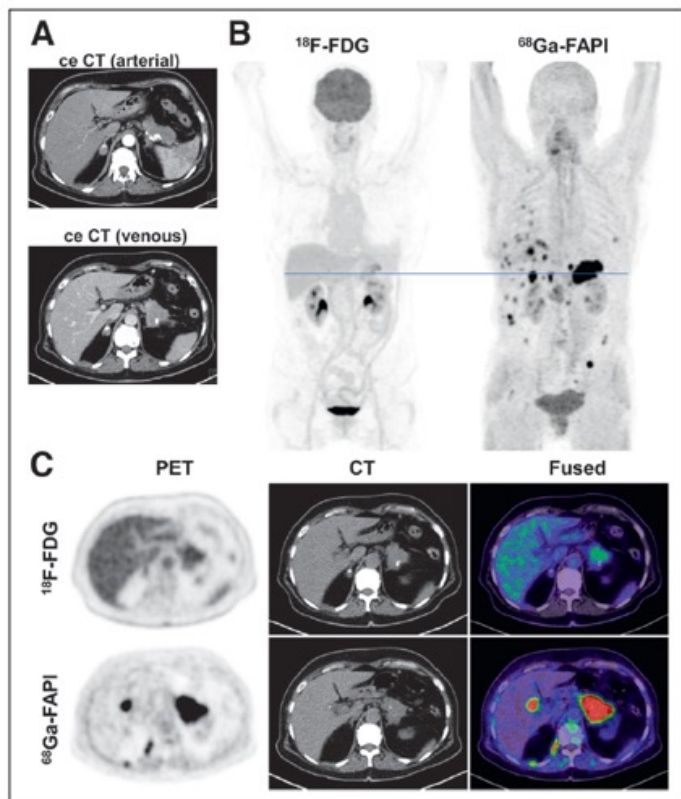


SOFIE holds diagnostic/companion diagnostic right of use for FAPI family of compounds

## JNM Best Clinical Article in 2021

### Impact of $^{68}\text{Ga}$ -FAPI PET/CT Imaging on the Therapeutic Management of Primary and Recurrent PDAC

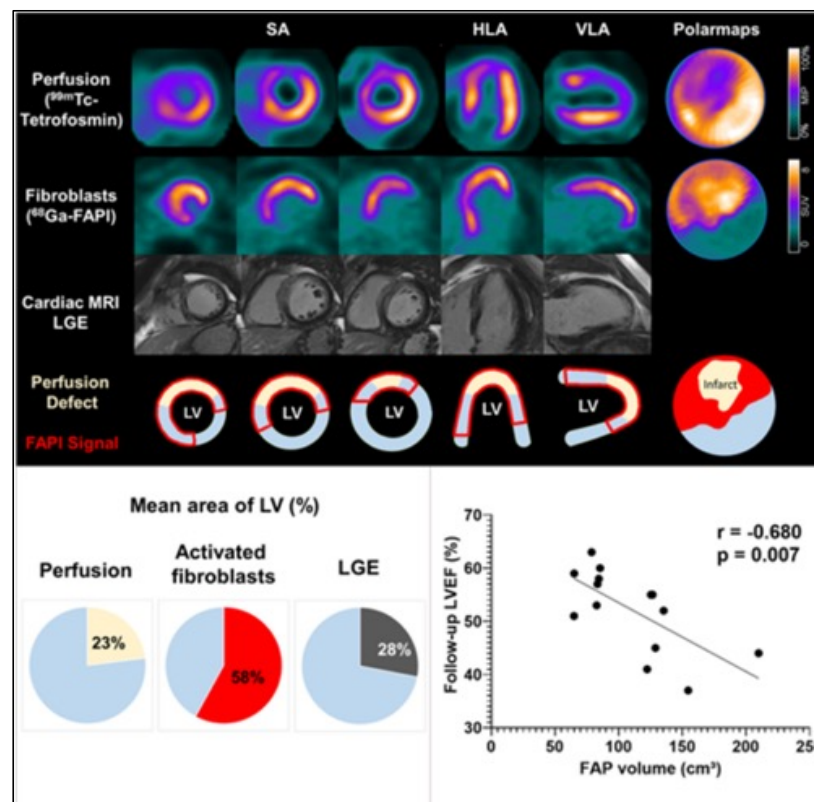
$^{68}\text{Ga}$ -FAPI PET/CT results led to changes in TNM staging in 10 of 19 patients



Röhrich M, Naumann P, Giesel FL, Choyke PL, Staudinger F, Wefers A, Liew DP, Kratochwil C, Rathke H, Liermann J, Herfarth K, Jäger D, Debus J, Haberkorn U, Lang M, Koerber SA. Impact of  $^{68}\text{Ga}$ -FAPI PET/CT Imaging on the Therapeutic Management of Primary and Recurrent Pancreatic Ductal Adenocarcinomas. J Nucl Med. 2021 Jun 1;62(6):779-786

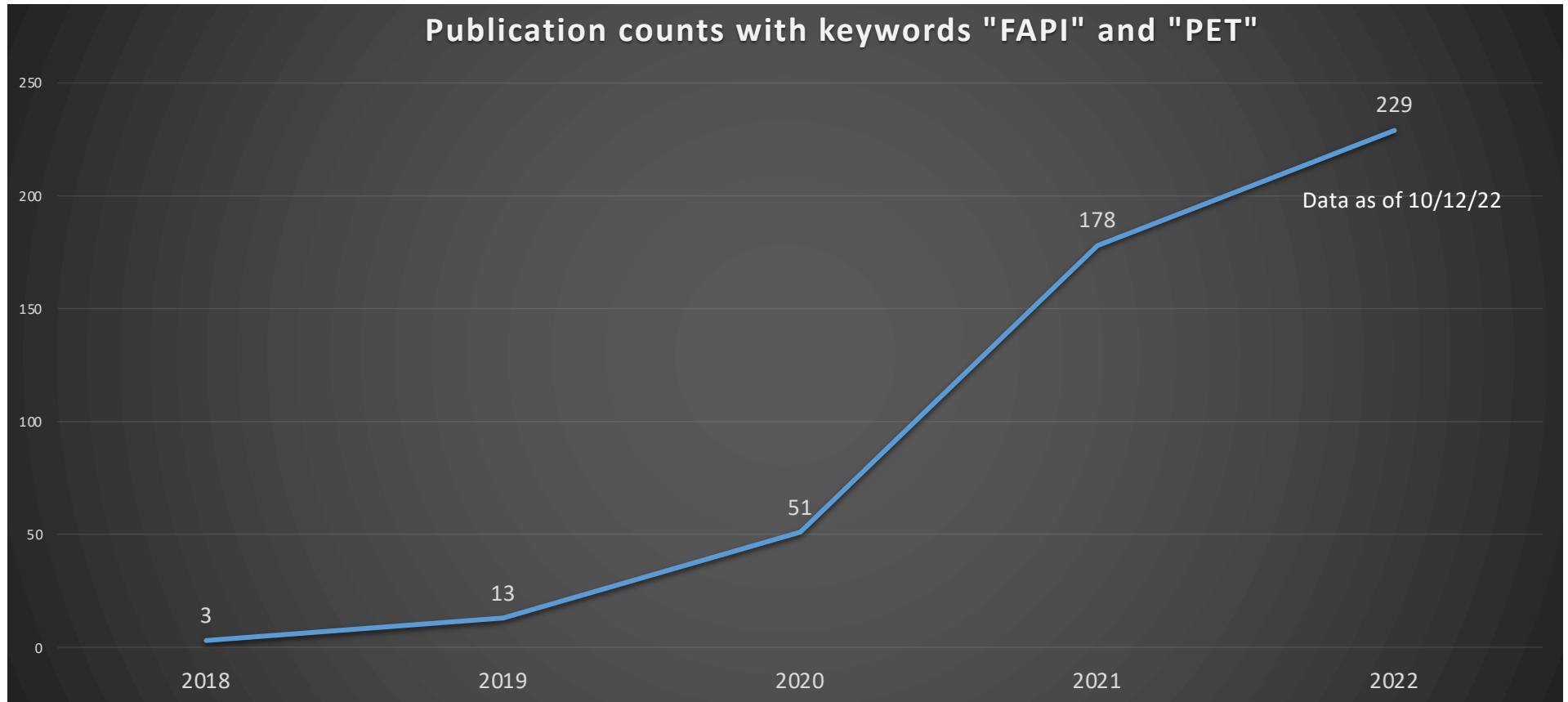
## SNMMI Image of the Year 2022

### Representative case with acute anterior wall myocardial infarction: $^{68}\text{Ga}$ -FAPI-46




Johanna Diekmann, James Thackeray, Thorsten Derlin, Christoph Czerner, Tobias Ross, and Frank Bengel, Department of Nuclear Medicine, Hannover Medical School, Hannover, Niedersachsen, Germany; and Tobias Koenig, Jonas Neuser, Andreas Schaefer, Jochen Tillmans, and Johann Bauersachs, Department of Cardiology and Angiology, Hannover School of Medicine, Hannover, Niedersachsen, Germany.

# Mounting interest in FAPI



# Publication analysis

  
# of patients reported

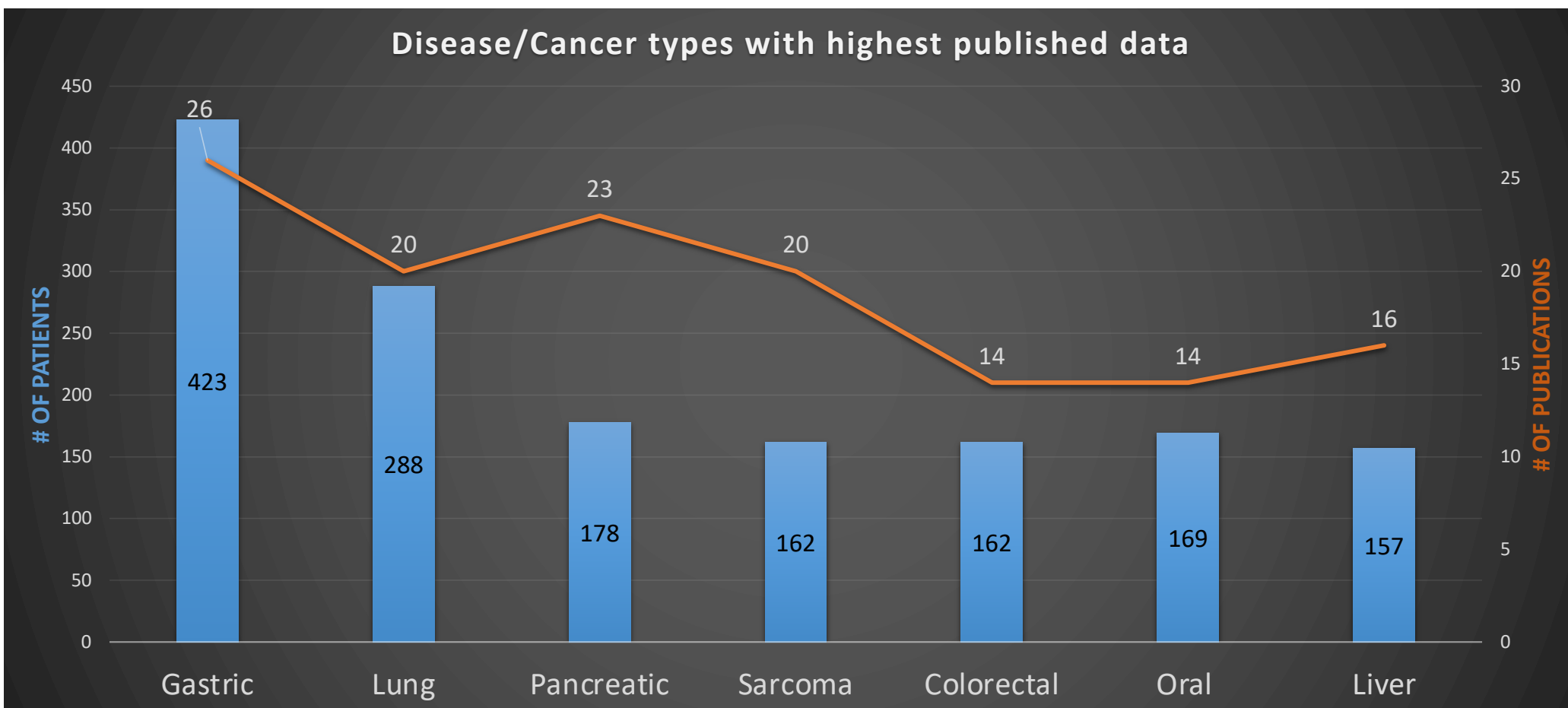
Total Publications with ALL FAP targeted radiopharmaceuticals	Publications with FAPI family of compounds	
4451	4033	91%
	3067- Oncology	
	966- non-oncology	
	323	85%

  
# of publications

Takeaway: FAPI family of compounds comprise the majority of publications and patient reported data to date. *(Review articles are excluded)*

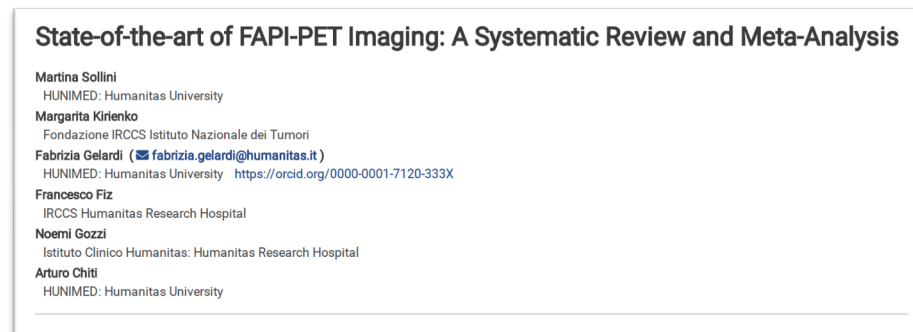
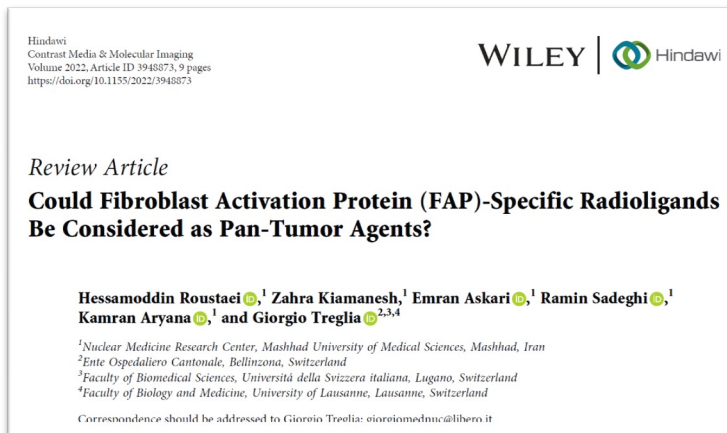
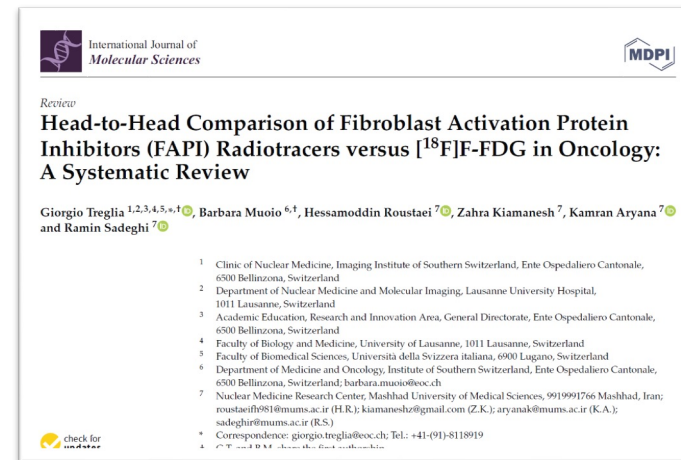
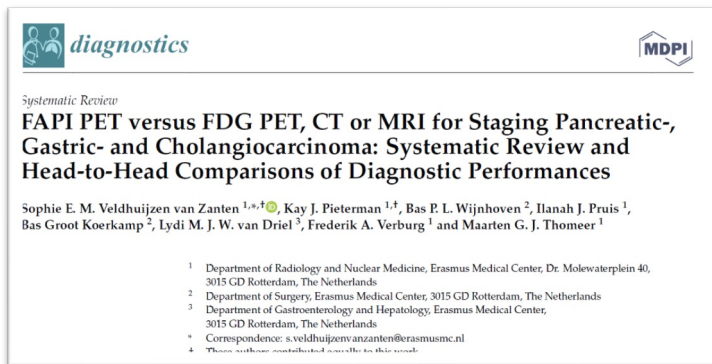
# Publication analysis

Diseases/cancers with the highest # of patients (>150) reported with FAPI compounds



# Meta Data Analysis of FAP radioligands in imaging

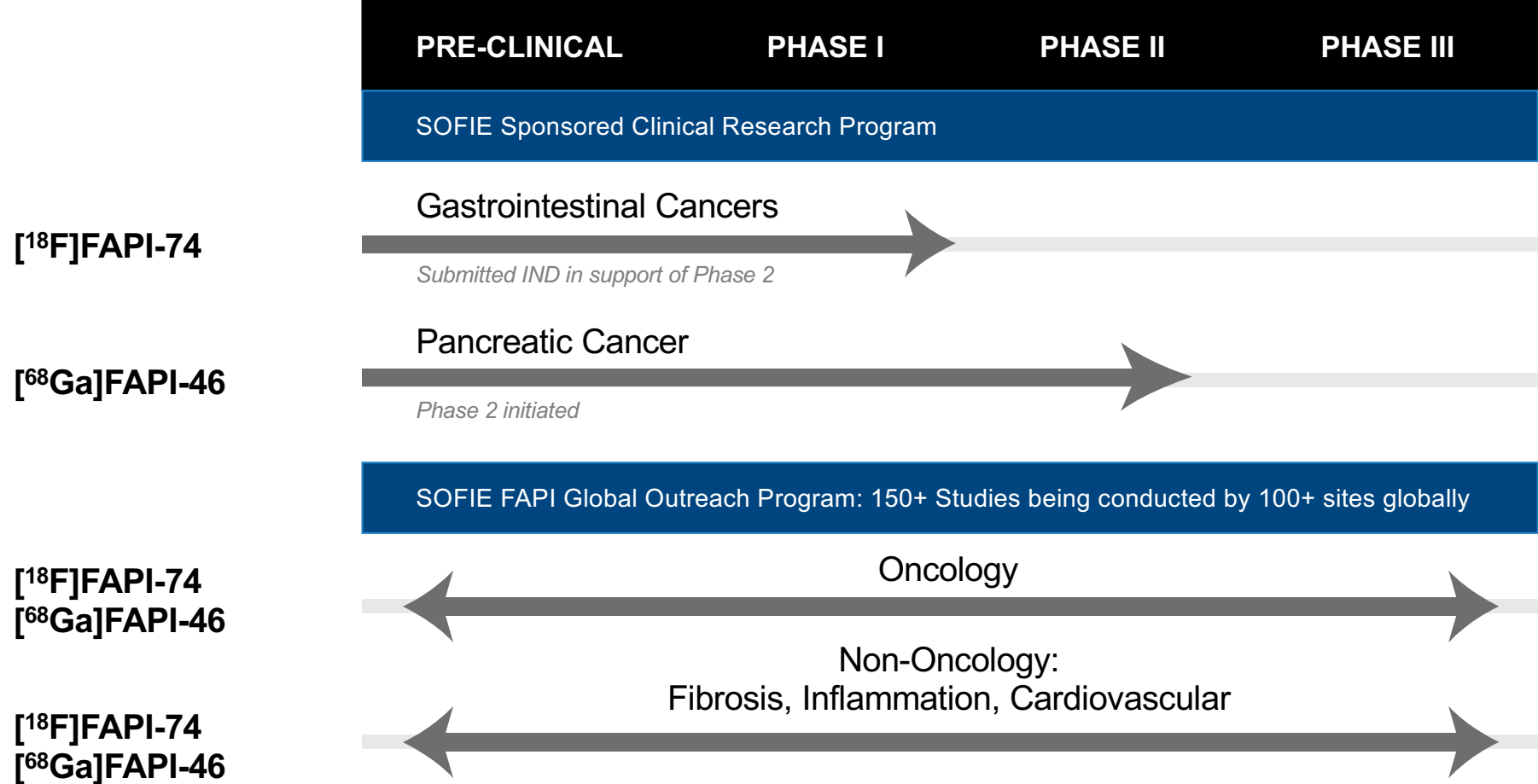
Takeaway: strong prelim data of performance in various cancers, especially GI/biliary/liver

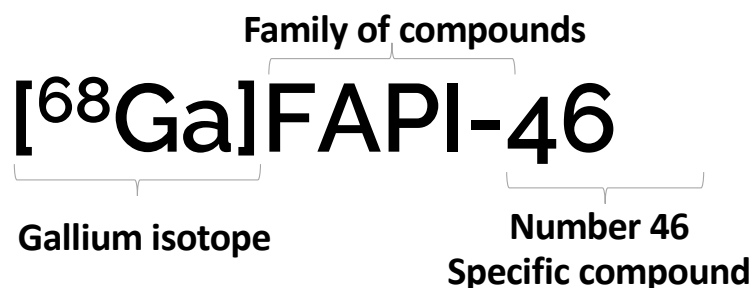


SOFIE clinical studies focusing on unmet need in GI cancers

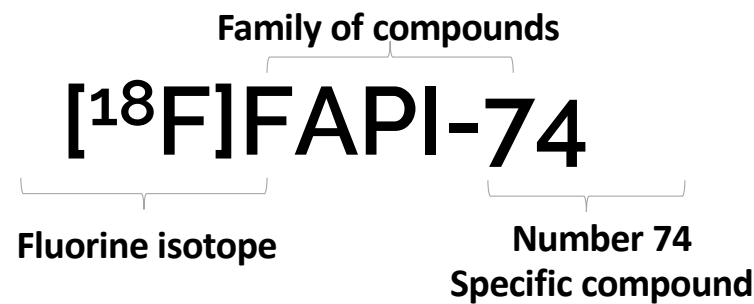


# SOFIE's Product Pipeline





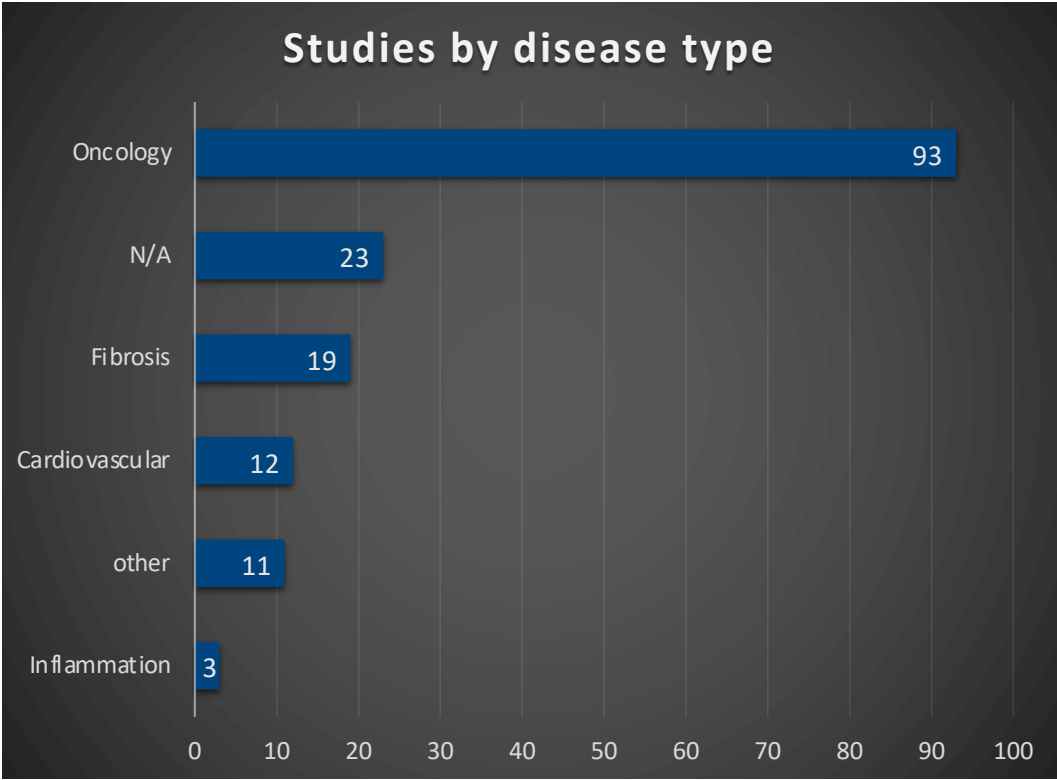
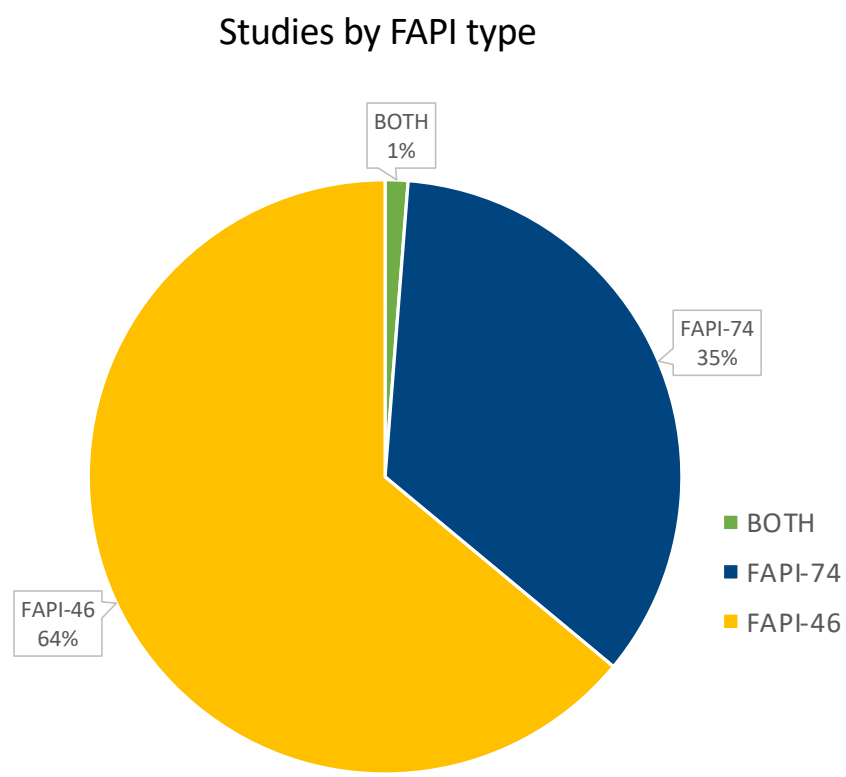
- Lead **gallium** labeled compound
- DOTA chelator in the molecular structure allows coupling of the FAPI molecules for theranostic use
- A **Phase 2**, Multicenter, Single Arm, Open Label, Non-Randomized Study of [<sup>68</sup>Ga]FAPI-46 PET in Patients with Resectable or Borderline Resectable **Pancreatic Ductal Adenocarcinoma**
- Total number of patients: **60**
- Activated sites: **NYU** and **Mayo Clinic**
- Upcoming site: UCLA
- ClinicalTrials.gov **NCT05262855**



- Lead **Fluorine 18** compound
- Broader applicability through 18-F radiolabeling
  - Provides advantage of a longer half life (2 hours)
  - Provides the capacity to support larger studies with high patient throughput
- **Automated synthesis** consumables available through Trasis for MiniAIO and AIO
- IND submitted **end of October** for Phase 2 study in GI cancers: Hepatocellular carcinoma, pancreatic, gastric cholangiocarcinoma, and colorectal cancer
- Site selection efforts are in progress pending FDA's acceptance of IND

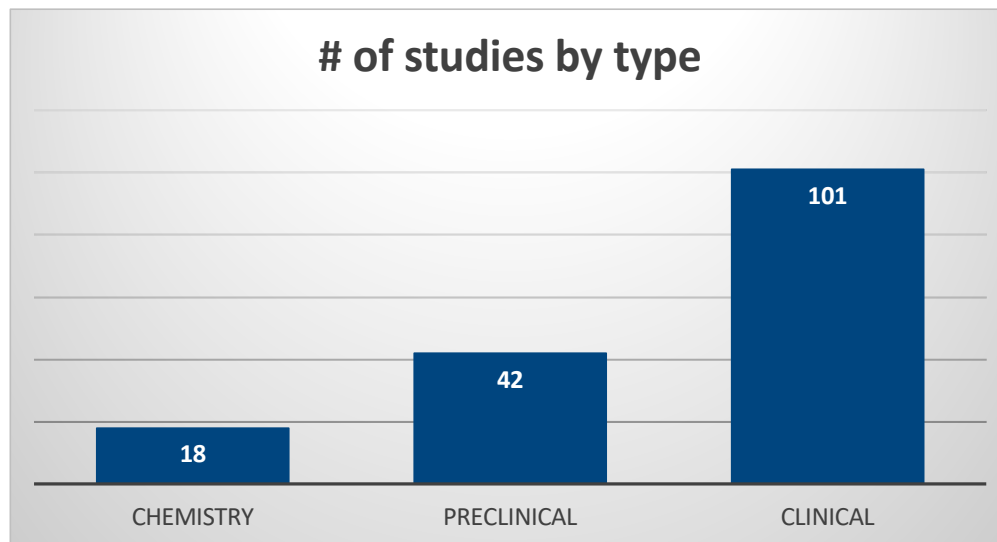


# Studies by FAPI type and Disease type



N/A: Chemistry studies with no specific disease indication  
Other: Other clinical indications not captured

# FAPI Global Outreach Program- Statistics



5131 Patients  
Planned

Patients imaged up to now  
1082

101 clinical studies globally underway with 5000+ patients

# SOFIE's FAPI Global Outreach Program

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's IND(s) or IND content to pursue investigator-initiated trial

Allows sites to expand their research program and grant opportunities

## Process for access to FAPI precursor

Introductory Call



Application Completion



Application Approval

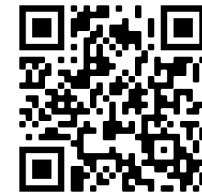


MTA Signature



Material Shipment

Complete application on our website: <https://sofie.com/pipeline/access/>



# Quote from SOFIE's trial- first PDAC patient imaged



*"I'd like to thank SOFIE and NYU Langone for making this valuable clinical trial possible. As a new cancer patient, and an IP lawyer with decades of experience representing companies, institutions and inventors in the health sciences industry, I recognize the importance of patient participation in clinical trials, and am happy to have had the opportunity to make a small but meaningful contribution to this important research."*



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Thank you for  
your attention!

For questions, please email:  
[Sherly.Mosessian@sofie.com](mailto:Sherly.Mosessian@sofie.com)



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