[68Ga]FAPI-46 Phase 2 clinical development updates

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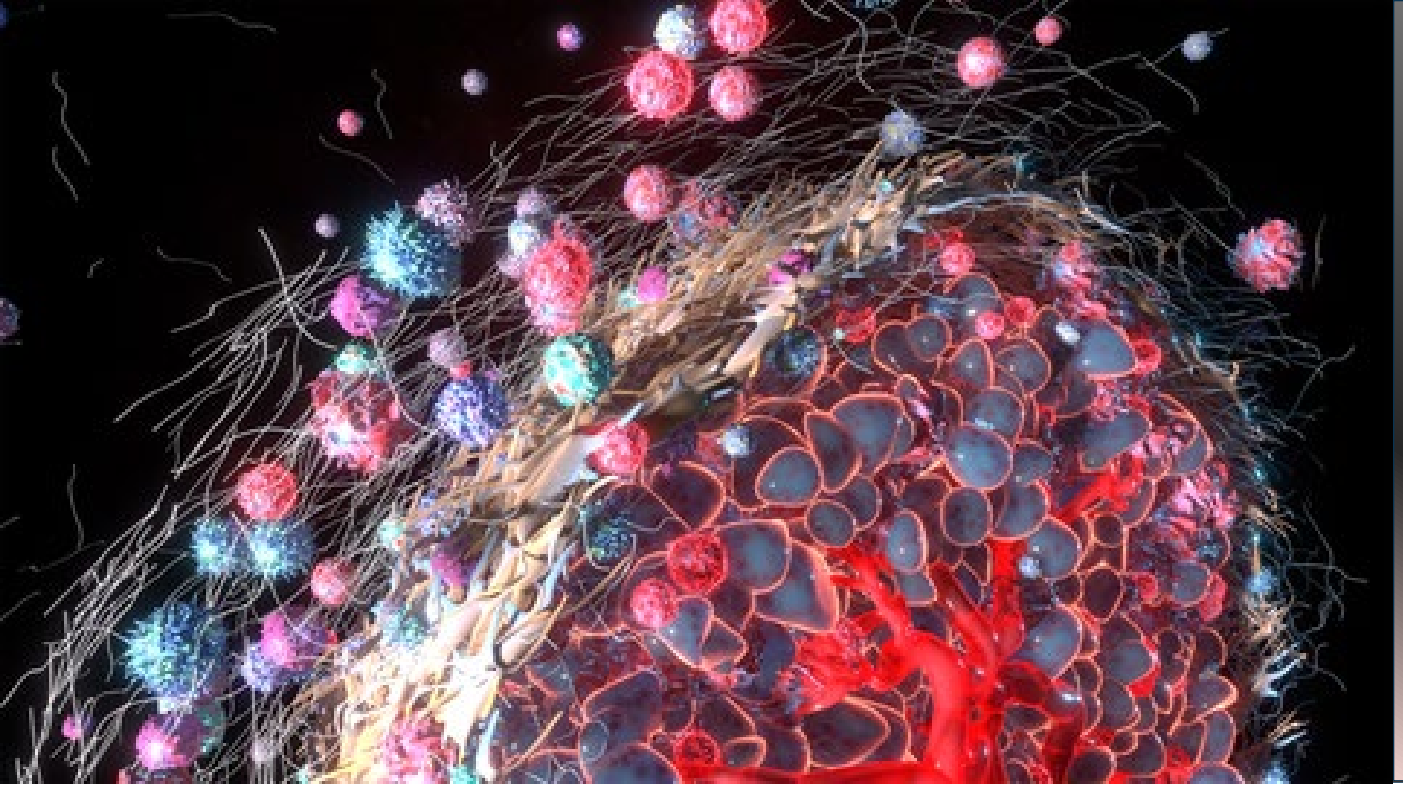


SOFIE and GE HealthCare enter licensing agreement to develop FAP PET Radiotracers

A global licensing agreement has been signed for the development and commercialization of SOFIE's two investigational products: [^{68}Ga]FAPI-46 and [^{18}F]FAPI-74.

What this means for [^{68}Ga]FAPI-46:

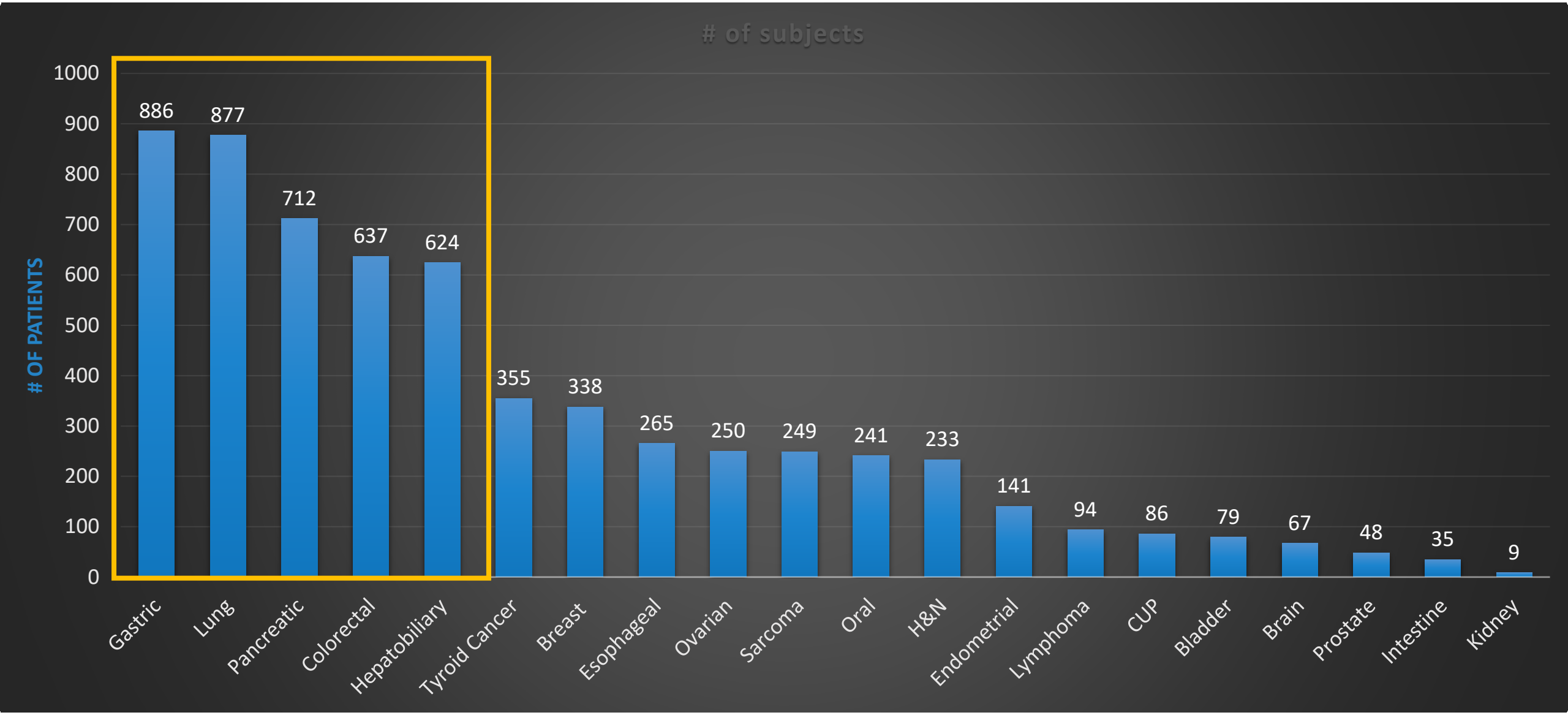
- GE HealthCare to take global [^{68}Ga]FAPI-46 rights
- SOFIE continues execution of the study as the Sponsor
- Joint Steering Committee of GE HealthCare and SOFIE members formed for decision making

Publication analysis

	Total Publications/Patients with ALL FAP targeted radiopharmaceuticals	Publications/Patients with FAPI family of compounds	
 # of patients reported	9,848	9,048	92%
		7,000- Oncology 2,048- Non-Oncology	
 # of publications	748	650	87%

Takeaway: FAPI family of compounds comprise the majority of publications and patient reported data to date (March 2024). *(Review articles are excluded)*

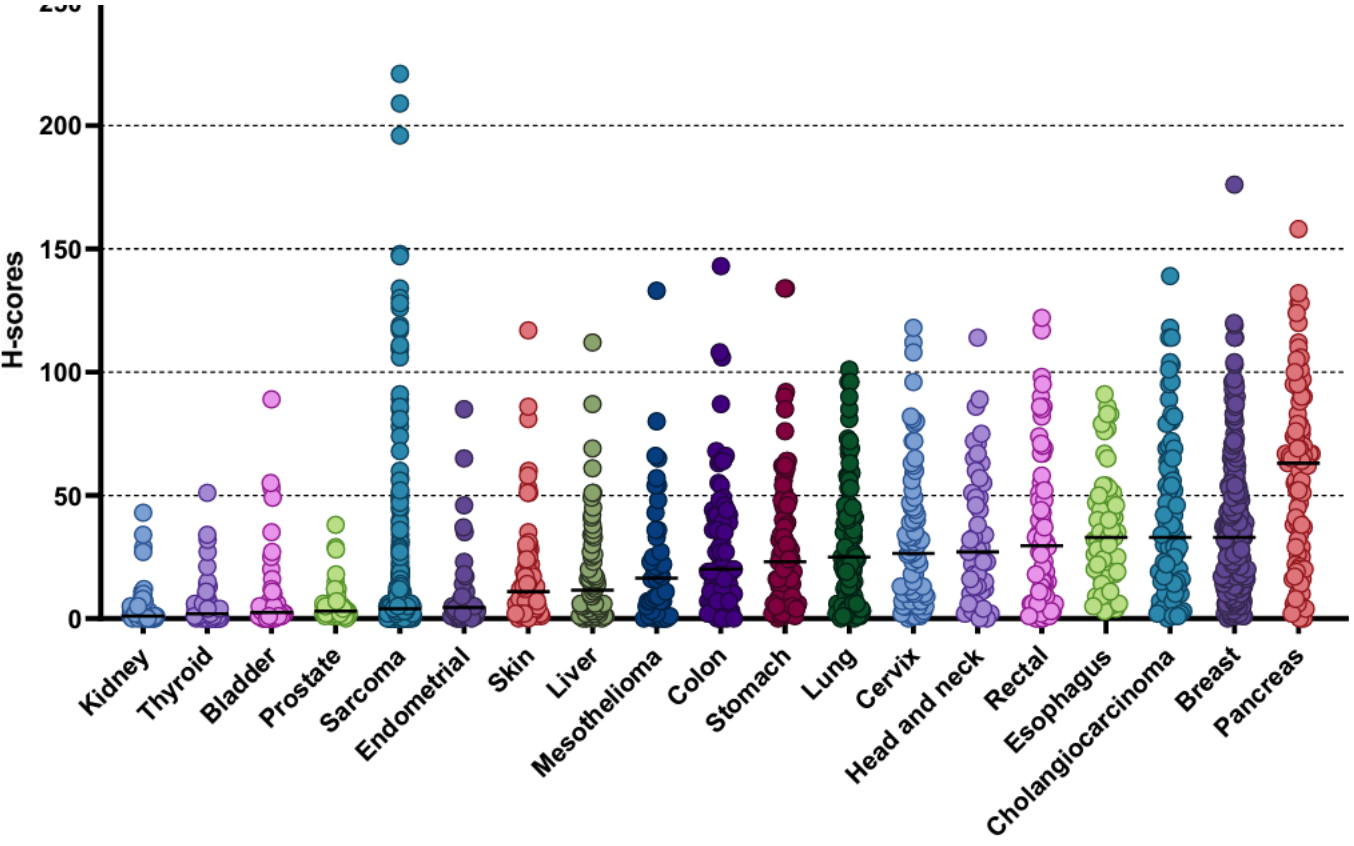
of patients published in various oncologic disease

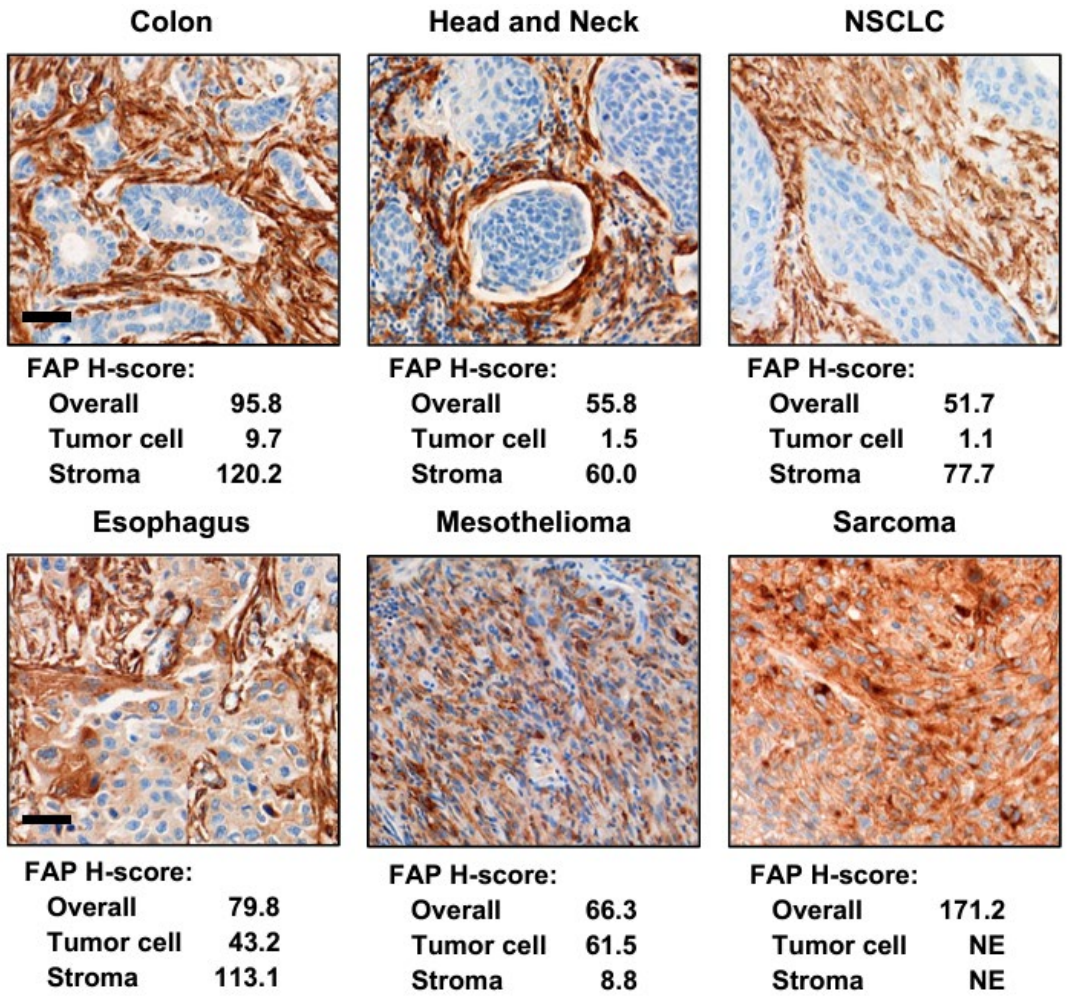


GI cancers encompass majority of the patient numbers reported with FAPI

FAP expression in human solid cancers

FAP is a great target due to its overexpression in most of the cancer types (90%)

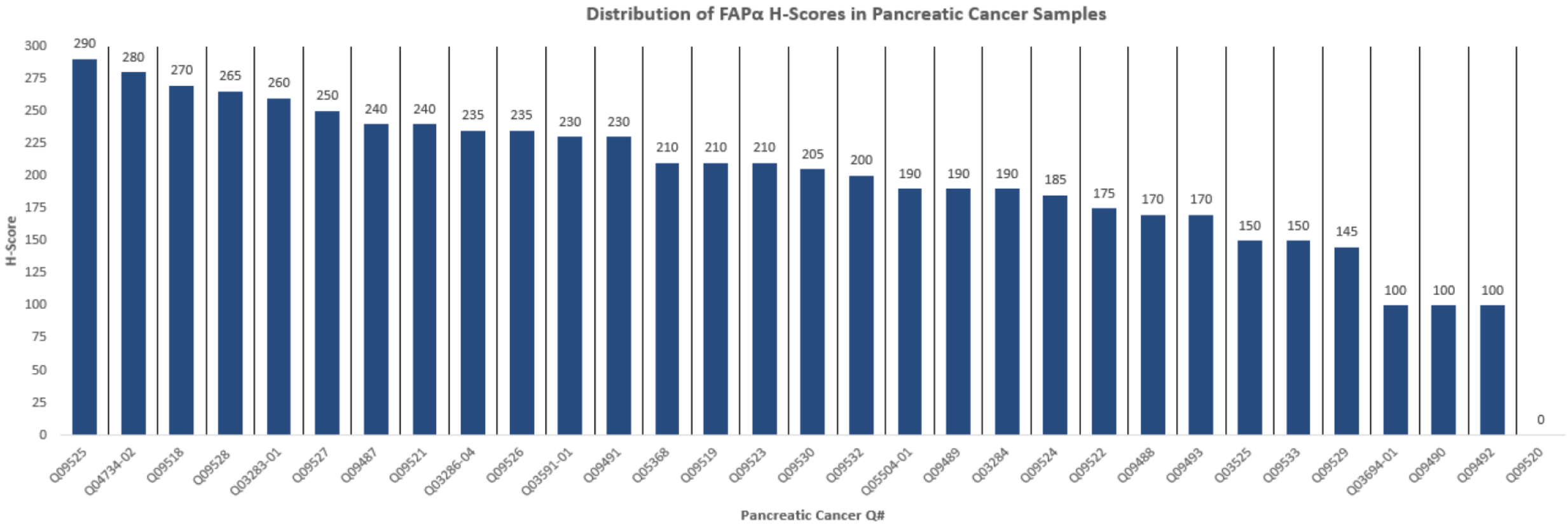




Zboralski D et.al. Eur J Nucl Med Mol Imaging. 2022 Sep;49(11):3651-3667. doi: 10.1007/s00259-022-05842-5. Epub 2022 May 24. PMID: 35608703.

NE, not evaluable

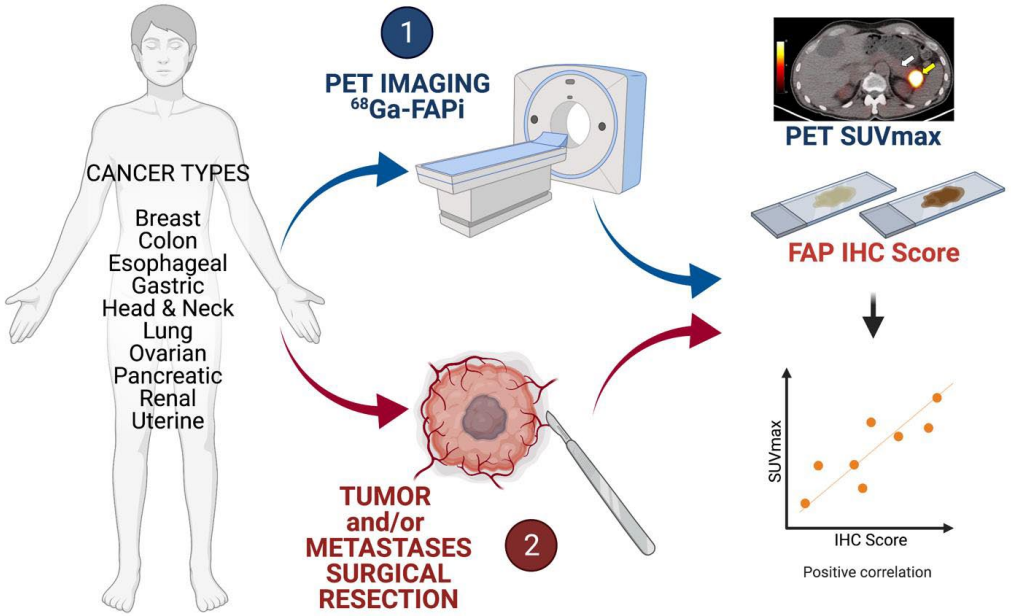
Proof of concept FAP IHC on pancreatic cancer tissue

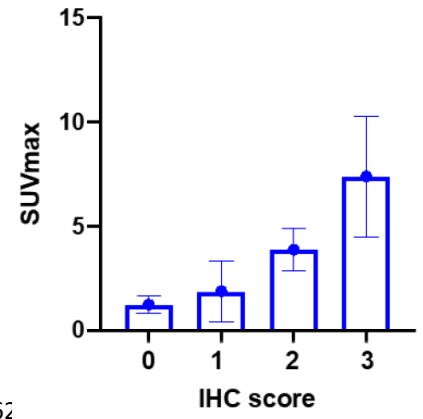


SOFIE conducted study with DLS

FAP IHC and PET signal validation- 2 independent studies for [^{68}Ga]FAPI-46

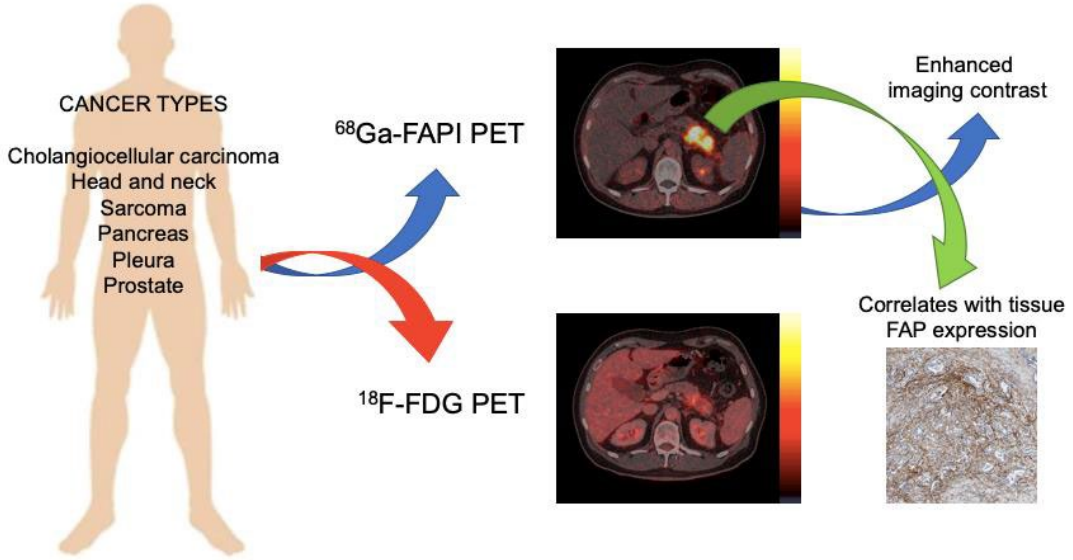
Correlation between FAP immunohistochemistry score and ^{68}Ga-FAPI-46 PET SUVs across cancer and non-cancer tissues

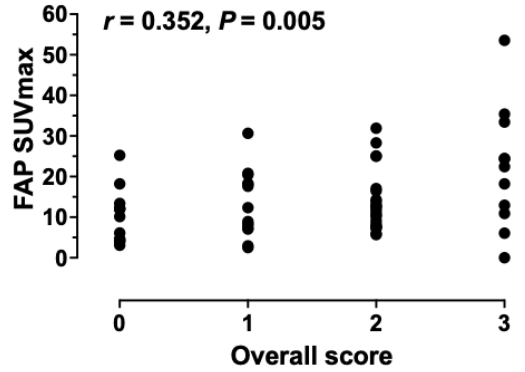




Mona et al. 2021 doi: 10.2967/jnumed.121.262

Fibroblast activation protein positron emission tomography and histopathology in a single-center database of 324 patients and 21 tumor entities





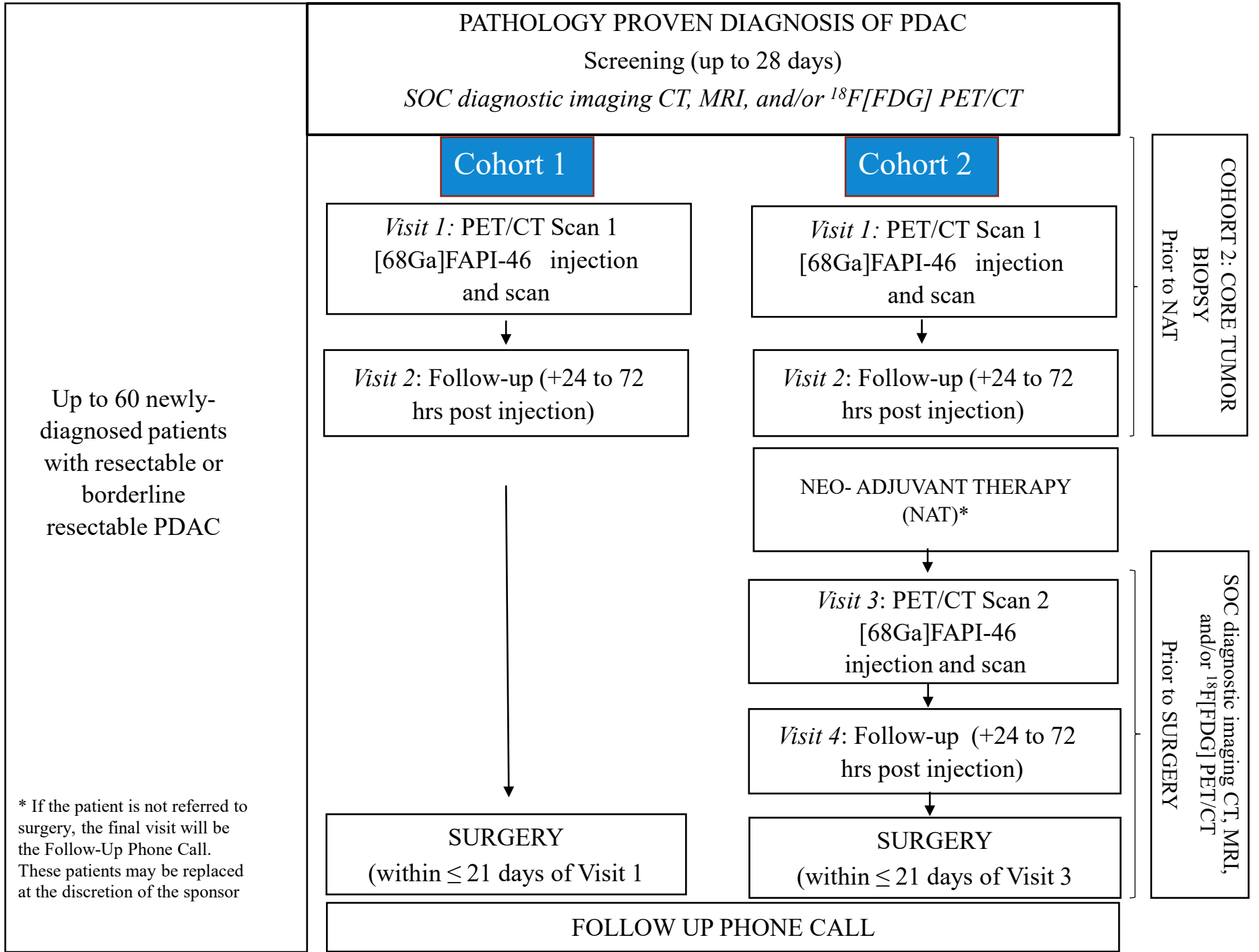
Hirmas et al.2022 doi: 10.2967/jnumed.122.264689

Clinical Protocol

[^{68}Ga]-FAPI-46 Phase 2 in PDAC

- A **Phase 2**, Multicenter, Single Arm, Open Label, Non-Randomized Study of [68Ga]FAPI-46 PET in Patients with Resectable or Borderline Resectable Pancreatic Ductal Carcinoma (PDAC)
- Total number of patients: **60**
- Anticipated duration: **2 years**
- All sites are in the United States.
- Two cohorts of patients are included in this study:
  - Cohort 1: PDAC diagnosed patients who will go to surgery without NAT
  - Cohort 2: PDAC diagnosed patients who will go through NAT prior to surgery

Study Schematic



Objectives of the study

Primary Objective:

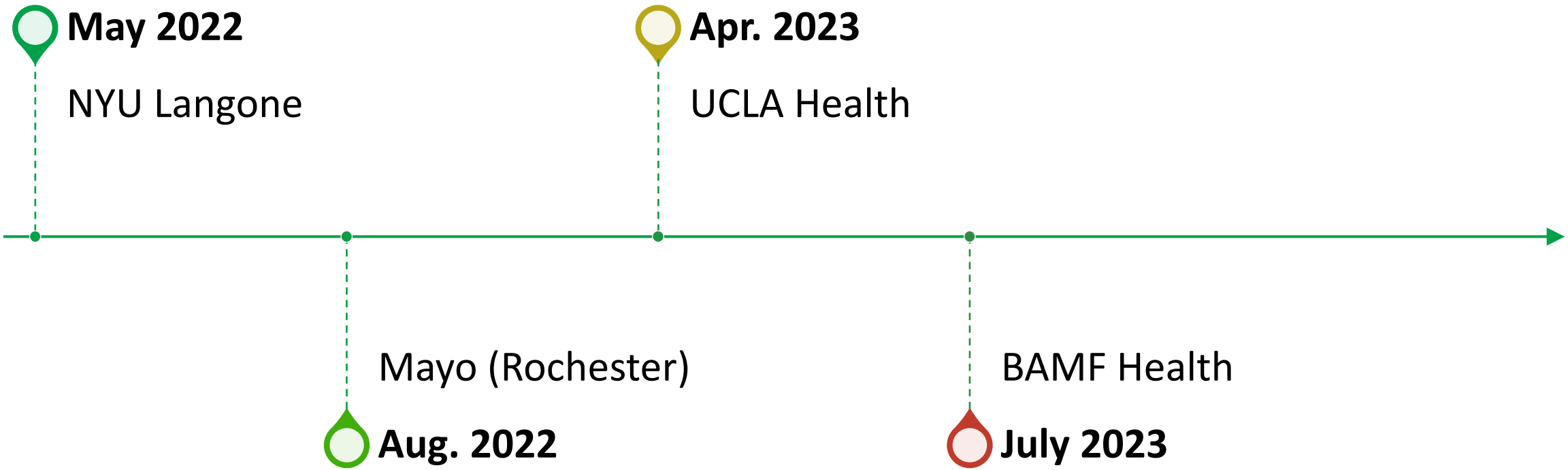
1. Evaluate the performance [sensitivity, specificity, accuracy] of [68Ga]FAPI-46 PET imaging to detect FAP-expressing cells, using histopathology as truth standard.

Secondary Objectives:

1. Evaluate positive and negative predictive values, as well as accuracy of [68Ga]FAPI-46 PET images, to detect FAP-expressing cells using histopathology as truth standard.
2. Correlate histopathology with FAP staining on FAP IHC assay.
3. Further characterize the safety profile of [68Ga]FAPI-46 in patients with PDAC.

Exploratory Objectives

1. Compare the detection of local and metastatic disease using [68Ga]FAPI-46 PET to a composite of clinical, radiological (i.e. CT, MR) and/or 18F-FDG PET and histopathological reference in patients with resectable or borderline resectable PDAC.
2. Compare pre- and post-treatment [68Ga]FAPI-46 PET evaluations obtained in Cohort 2 to identify perturbations, if any, from neoadjuvant therapy.



- NYU Langone and Mayo have completed patient recruitment.
- UCLA and BAMF Health actively recruiting subjects to complete the Phase 2

Family of compounds

[^{68}Ga]FAPI-46

Gallium-68 isotope Compound #46

Phase 2 in patients with Pancreatic Ductal Adenocarcinoma (PDAC)

68 minutes half life

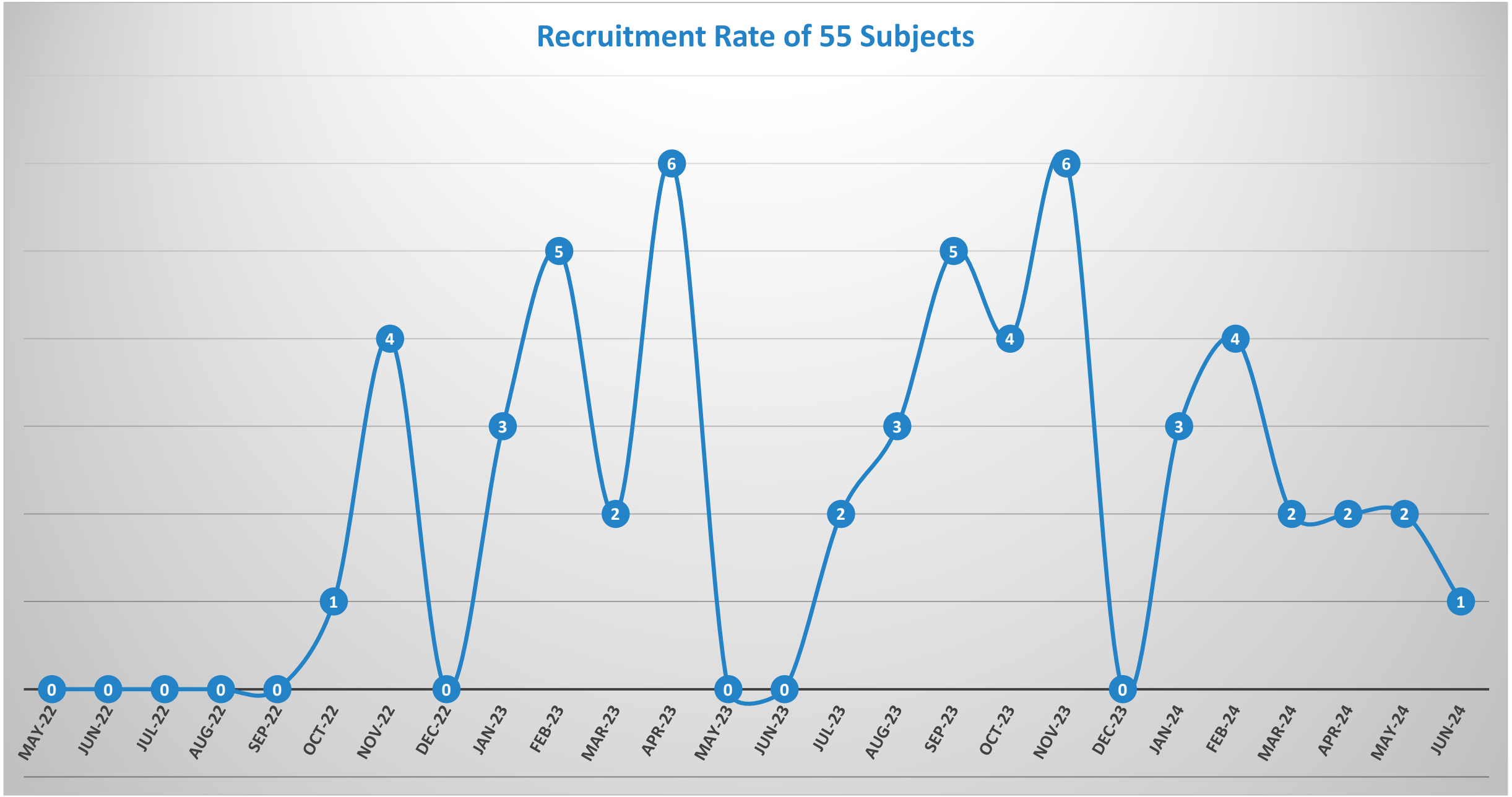
4 sites activated
- NYU Langone - Completed
- Mayo Clinic - Completed
- UCLA
- BAMF Health

60 patients planned
- **55** patients imaged with min 1 FAPI

Lead Gallium-68 product

Can be utilized for theranostic use

Study launched May 2022


Recruitment Rate of 55 Subjects
0
0
0
0
0
1
4
0
3
5
2
6
0
0
2
3
5
4
6
0
3
4
2
2
2
1
MAY-22
JUN-22
JUL-22
AUG-22
SEP-22
OCT-22
NOV-22
DEC-22
JAN-23
FEB-23
MAR-23
APR-23
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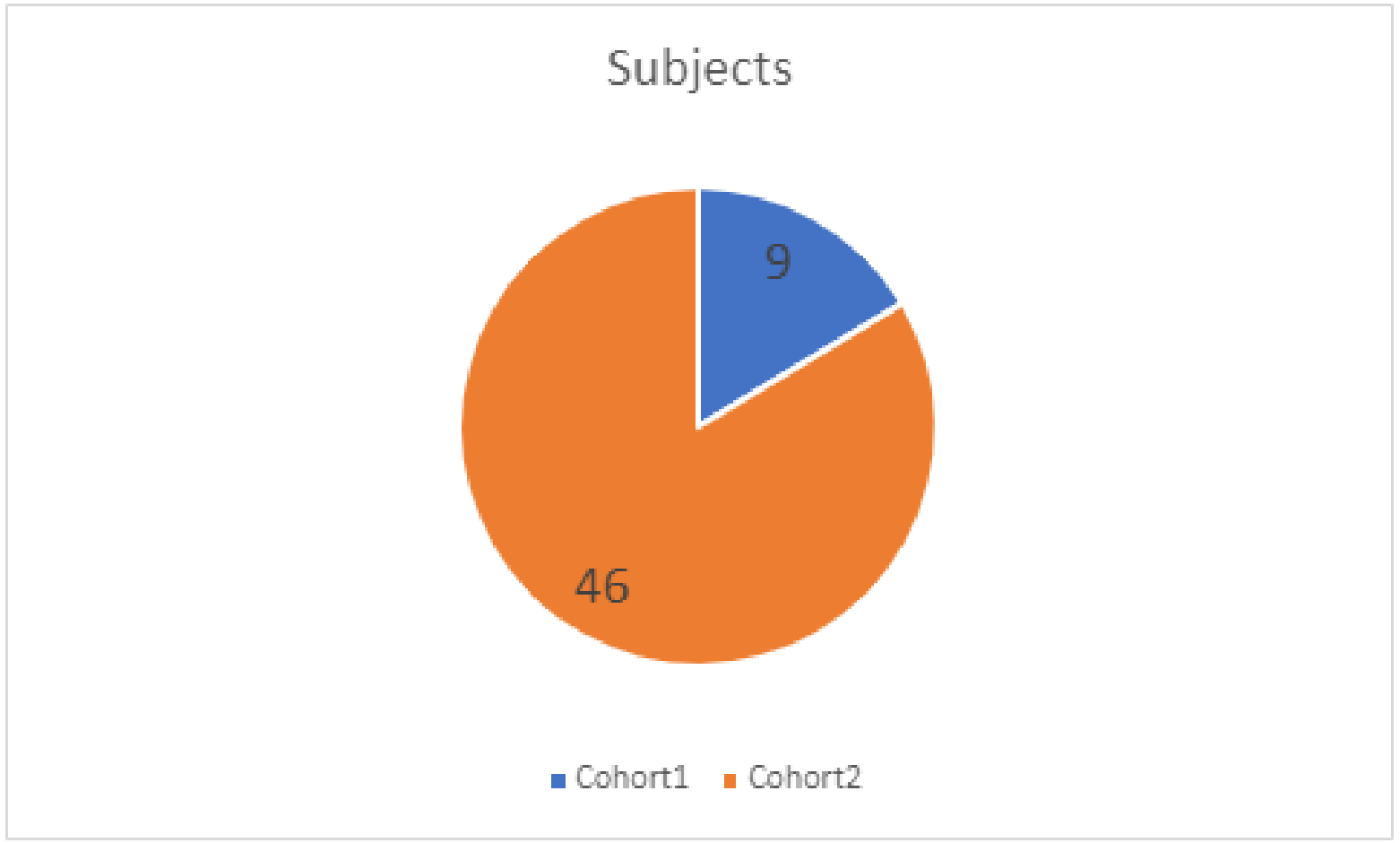
MAY-24
JUN-24

68Ga-FAPI-46 overview-
55 patients recruited with 1 FAPI scan



Takeaways

- Subject recruitment is progressing on schedule for the study
- We have a good mix of cohort 1 and cohort 2 subjects, along with respective tissue for analysis
- The Last Subject Visit is anticipated to take place in the next 9 months, followed by data analysis and end of phase 2 meeting with FDA
- Phase 3 planning efforts are underway

Tumor Characterization by [68Ga]FAPI-46 PET/CT Can Improve Treatment Selection for Pancreatic Cancer Patients: An Interim Analysis of a Prospective Clinical Trial

Rasinski P et.al. Tumor Characterization by [^{68}Ga]FAPI-46 PET/CT Can Improve Treatment Selection for Pancreatic Cancer Patients: An Interim Analysis of a Prospective Clinical Trial. J Nucl Med. 2023 Aug;64(8):1232-1237

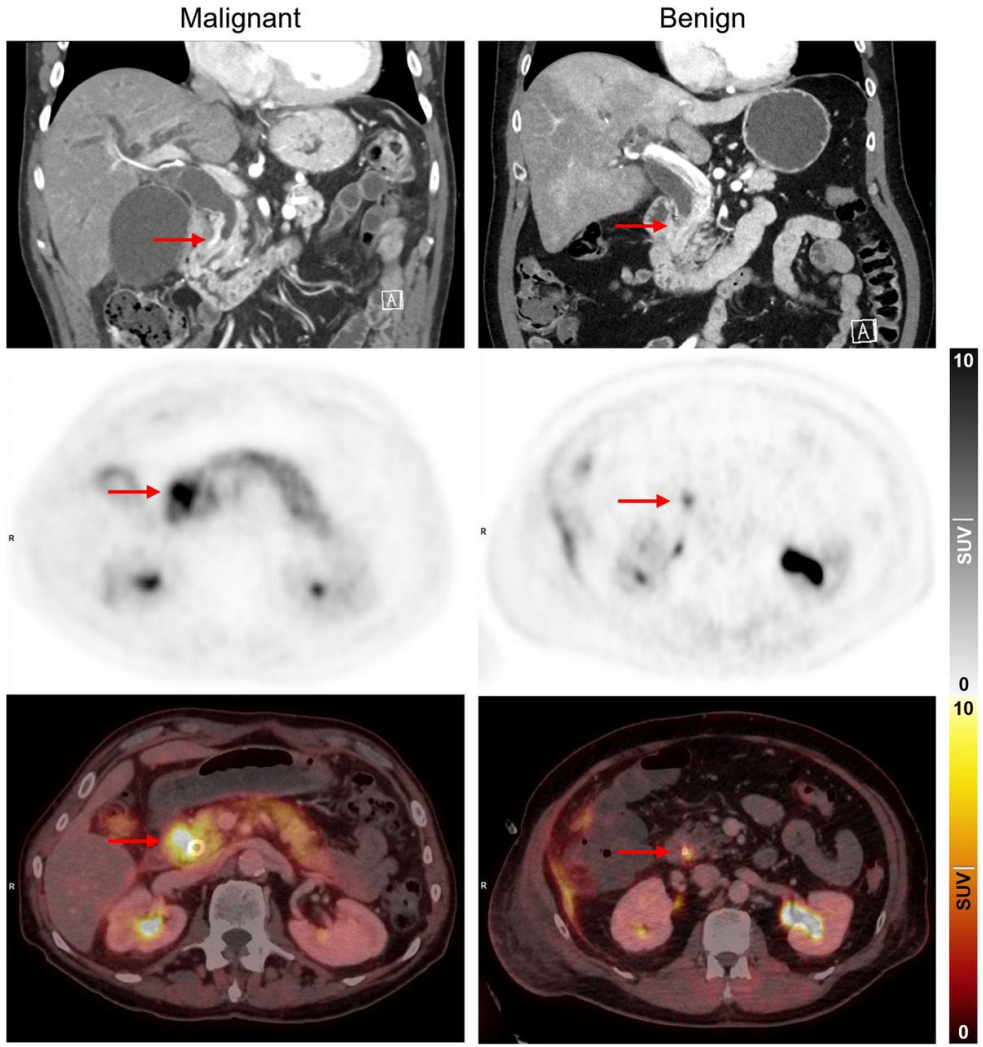


TABLE 2

SUV_{max} and SUV_{mean} in Pancreatic Lesions with Malignant Vs. Benign Histopathology

	Malignant		Benign		
Parameter	Mean ± SD	Range	Mean ± SD	Range	*P*
SUV_{max}	17.0 ± 5.0	9.9–24.9	5.0 ± 5.0	1.0–15.4	<0.001
SUV_{mean}	10.0 ± 2.7	5.9–15.0	2.8 ± 2.6	0.5–8.2	<0.001

TABLE 3

Diagnostic Performance of SUV_{max} with Cutoff of 10.2 and SUV_{mean} with Cutoff of 5.9 in Diagnosis of PC

	Whole cohort (n = 30)		Subcohort with equivocal clinical imaging (n = 11)	
Parameter	SUV_{max}	SUV_{mean}	SUV_{max}	SUV_{mean}
Sensitivity	95 (75–100)	100 (83–100)	100 (29–100)	100 (29–100)
Specificity	80 (44–97)	80 (44–97)	100 (63–100)	100 (63–100)
Positive predictive value	90 (70–99)	91 (71–99)	100 (29–100)	100 (29–100)
Negative predictive value	89 (52–100)	100 (63–100)	100 (63–100)	100 (63–100)
Overall accuracy	90 (73–98)	93 (78–99)	100 (72–100)	100 (72–100)

Data are percentages, with 95% CIs in parentheses.


Development
Leading the clinical development of [68Ga]FAPI-46 and [18F]FAPI-74. SOFIE's studies are in prospective Phase 2 trials in the United States.
SOFIE Sponsored Trials
PRE-CLINICAL
PHASE I
PHASE II
PHASE III
Gastrointestinal Cancers
Pancreatic Cancer
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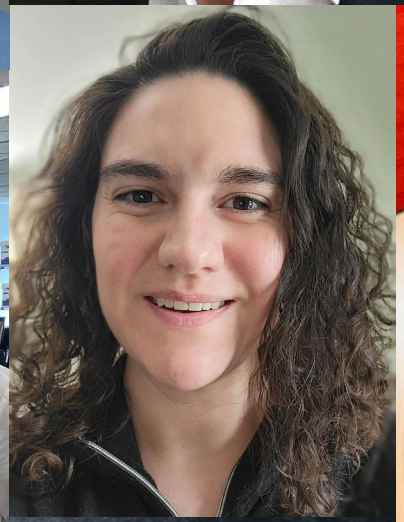


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NUCLEAR MEDICINE RECEIVING ROOM


LAS VEGAS
NEVADA
1905

Thank you