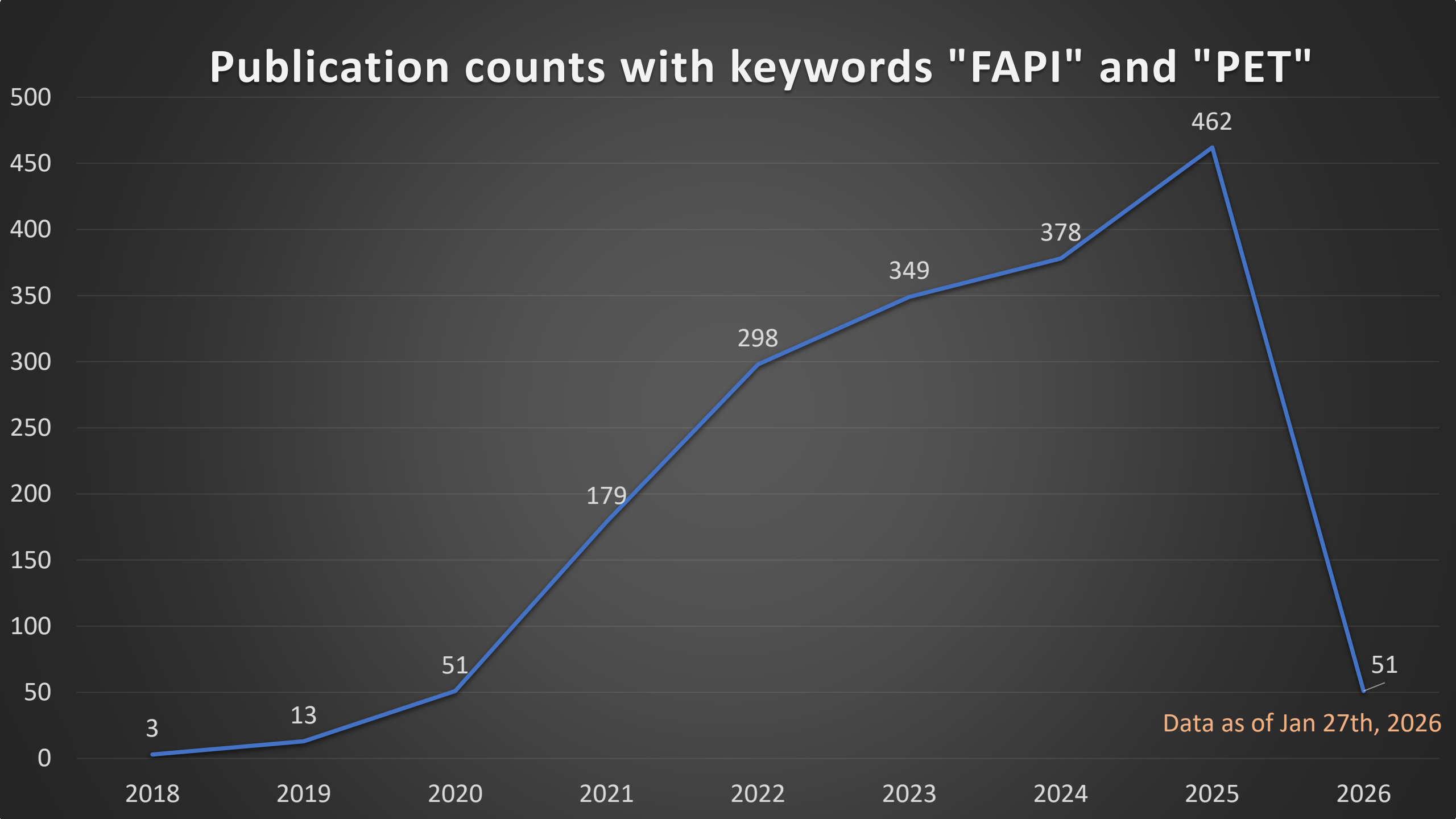
SOFIE
From start to clinic

8TH THERANOSTICS WORLD CONGRESS

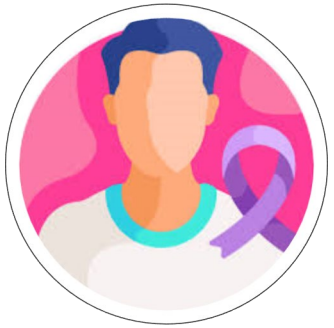
Sat, January 31, 2026 | 15:30 – 17:00 | TME Diagnostics

Addressing Unmet Needs with [^{18}F]FAPI-74

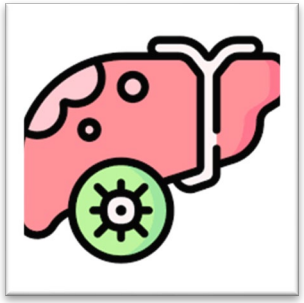
Sherly Mosessian, Ph.D.
Chief Scientific Officer
SOFIE


Publication counts with keywords "FAPI" and "PET"
500
450
400
350
300
250
200
150
100
50
0
3
13
51
179
298
349
378
462
51
2018
2019
2020
2021
2022
2023
2024
2025
2026
Data as of Jan 27th, 2026

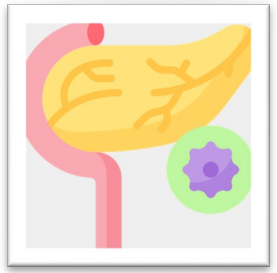
Published patient data with FAPI



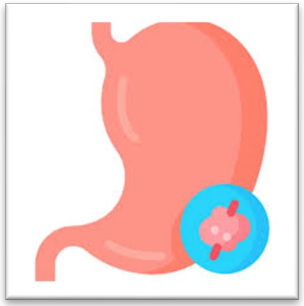
> 11,000 patients published with FAPI family of compounds



> 800 hepatobiliary cancer patients imaged with FAPI PET (>55 papers)



> 1,100 pancreatic cancer patients imaged with FAPI PET (>60 papers)



> 1,100 gastric cancer patients imaged with FAPI PET (>60 papers)

> 700 colorectal cancer patients imaged with FAPI PET (>40 papers)

Meta Data Analysis with FAPI suggests strong diagnostic performance in GI cancers

diagnostics
MDPI

Systematic Review

FAPI PET versus FDG PET, CT or MRI for Staging Pancreatic-, Gastric- and Cholangiocarcinoma: Systematic Review and Head-to-Head Comparisons of Diagnostic Performances

Sophie E. M. Veldhuijzen van Zanten [1,*,†], Kay J. Pieterman [1,†], Bas P. L. Wijnhoven [2], Ilanah J. Pruis [1], Bas Groot Koerkamp [2], Lydi M. J. W. van Driel [3], Frederik A. Verburg [1] and Maarten G. J. Thomeer [1]

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[2] Department of Surgery, Erasmus Medical Center, 3015 GD Rotterdam, The Netherlands
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† These authors contributed equally to this work.

Front Oncol. 2023 Feb 17;13:1093861. doi: 10.3389/fonc.2023.1093861. eCollection 2023.

Comparison of ^{68}Ga-FAPI and ^{18}F-FDG PET/CT for the diagnosis of primary and metastatic lesions in abdominal and pelvic malignancies: A systematic review and meta-analysis

Xue Liu [1], Huiting Liu [1], Cailiang Gao [1], Wenbing Zeng [2]

Affiliations + expand

PMID: 36874127 PMCID: PMC9982086 DOI: 10.3389/fonc.2023.1093861

Wang et al.
European Journal of Medical Research (2023) 28:34
https://doi.org/10.1186/s40001-023-00997-9

European Journal of Medical Research

REVIEW Open Access

[^{68}Ga]Ga-FAPI-04 PET MRI/CT in the evaluation of gastric carcinomas compared with [^{18}F]-FDG PET MRI/CT: a meta-analysis

Yawen Wang[1†], Wenhao Luo[2†] and Ye Li[3*]

Meta-Analysis > Hell J Nucl Med. 2024 Jan-Apr;27(1):35-45. doi: 10.1967/s002449912703. Epub 2024 Apr 18.

Head to head comparison of ^{68}Ga-FAPI PET/CT with ^{18}F-FDG PET/CT in primary and metastatic lesions of gastric tumor: A systematic review and meta-analysis

Cailiang Gao [1], Huiting Liu, Lirong Zhou, Wei Huang, Xue Liu

Affiliations + expand

PMID: 38629816 DOI: 10.1967/s002449912703

International Journal of Molecular Sciences
MDPI

t J Mol Sci. 2023 Jun; 24(12): 10136.
ublished online 2023 Jun 14. doi: 10.3390/ijms241210136
PMCID: PMC10299436
PMID: 37373285

iagnostic Performance of Positron Emission Tomography with Fibroblast-Activating rotein Inhibitors in Gastric Cancer: A Systematic Review and Meta-Analysis

lessio Rizzo,[1] Manuela Racca,[1] Federico Garrou,[2] Elisabetta Fenocchio,[3] Luca Pellegrino,[4] Domenico Albano,[5] rancesco Dondi,[5] Francesco Bertagna,[5] Salvatore Annunziata,[6] and Giorgio Treglia[7,8,9,*]

frontiers in Oncology

Front Oncol. 2023; 13: 1202505.
Published online 2023 Jun 26. doi: 10.3389/fonc.2023.1202505
PMCID: PMC10332156
PMID: 37434980

Head-to-head comparison of ^{68}Ga-FAPI-04 PET/CT and ^{18}F-FDG PET/CT in the evaluation of primary digestive system cancer: a systematic review and meta-analysis

Jiqi Ouyang, [1,2] Peiwen Ding, [3,4] Runshun Zhang, [1,*] and Yuexia Lu [1,2]

Author information Article notes Copyright and License information PMC Disclaimer

Theranostics 2023, Vol. 13, Issue 13 4694

IVYSPRING INTERNATIONAL PUBLISHER

Theranostics

2023; 13(13): 4694-4710. doi: 10.7150/thno.88335

Research Paper

Evaluation of FAPI PET imaging in gastric cancer: a systematic review and meta-analysis

Dan Ruan[1], Liang Zhao[1], Jiayu Cai[1], Weizhi Xu[1], Long Sun[1], Jiayi Li[2,3✉], Jingjing Zhang[4,5], Xiaoyuan

Review Article

The Role of FAPI PET Imaging in Pancreatic Cancer: A Meta-analysis Compared with ^{18}F-FDG PET

Family of compounds

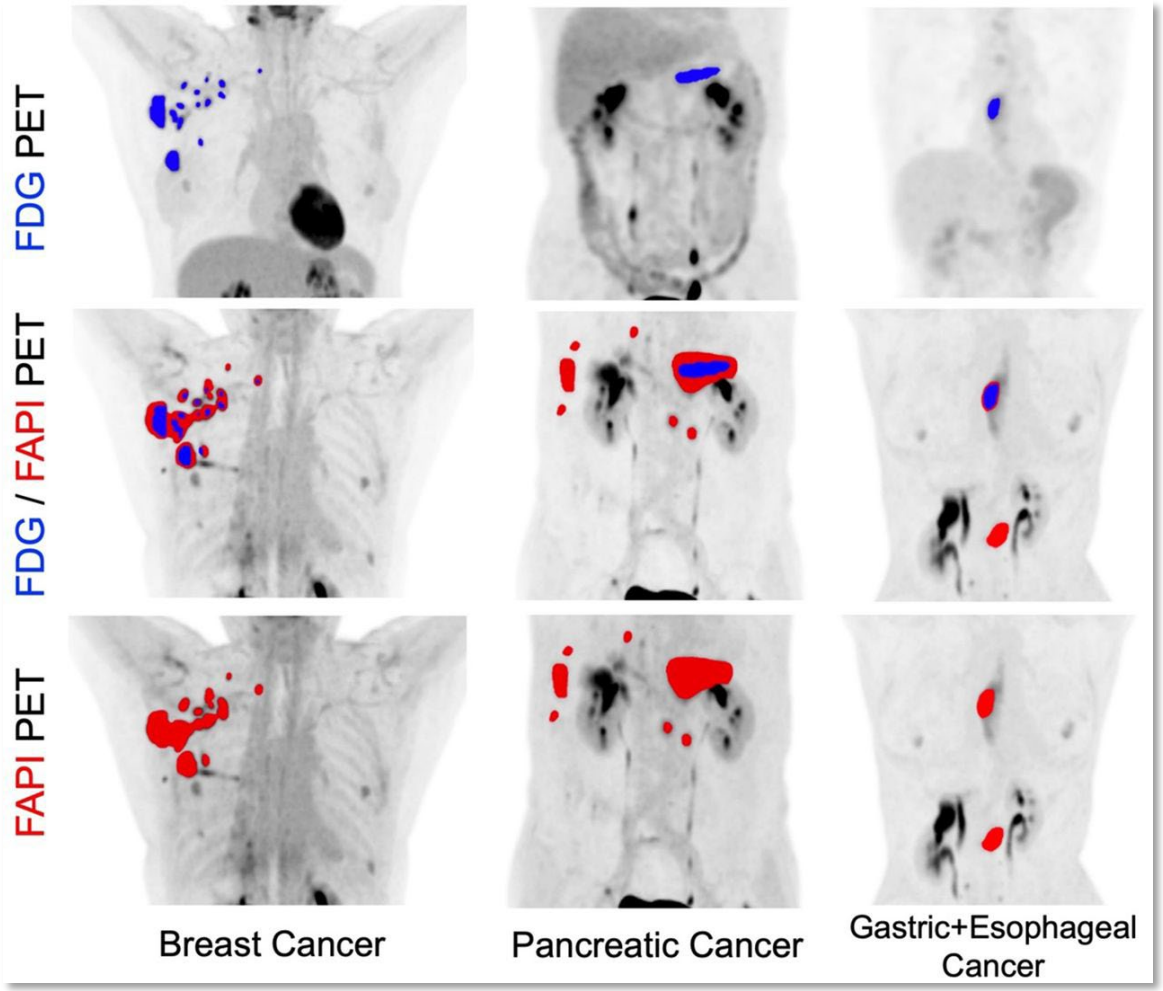
[^{18}F]-FAPI-74

Fluorine isotope

Number 74
Specific compound

- Created by Prof. Haberkorn lab (Heidelberg University)
- Lead F-18 product in FAPI family of compounds
- Being developed by SOFIE in the US
- Produced by SOFIE Network of Radiopharmacies

Green: Producing now **Orange**: 2026 go live



Tadashi Watabe et. al. Journal of Nuclear Medicine Aug 2023, 64 (8) 1225-1231; ***DOI:*** *10.2967/jnumed.123.265486*

[^{18}F]FAPI-74 Phase 2 Study in GI Cancer Patients-NCT05641896

First patient dosed
May 11, 2023

Last patient dosed
Jan 31, 2025

Phase 2 in patients with GI Cancers: hepatocellular carcinoma, gastroesophageal cancers, cholangiocarcinoma, colorectal cancer and pancreatic cancer

103 disease subjects imaged

- MGH
- MSKCC
- BAMF Health
- Northwell
- UCLA Health
- Mayo Rochester

Primary Endpoint - [^{18}F]FAPI-74 detecting FAP

*[18F]FAPI-74 PET demonstrated, in **100%** of cases, the ability to detect FAP when FAP was present in tissues.*
This validates [18F] FAPI-74 PET's ability to select patients based on presence of FAP.

Secondary Endpoint - [^{18}F]FAPI-74 detecting Disease

*[18F]FAPI-74 PET demonstrated, in **94%** of cases, the ability to detect disease when the disease was present.*
This validates [18F]FAPI-74 in detection of oncologic malignancies.

Gastric Cancer- [1]NCCN Guidelines

Modality	Primary disease	Lymph node	Preoperative staging	Peritoneal	Comments
Endoscopic Ultrasound					Indicated for assessing the depth of tumor invasion and nodal involvement
CT			 Accuracy: 53%		Best in initial and preoperative staging
FDG PET			 Accuracy: 47%		Used in preoperative staging and treatment response. Additive to CT
[2] Laparoscopy				 Sensitivity: 85% Specificity: 100%	

1 NCCN Guidelines Version 2.2025, 04/04/25 © 2025
2 https://www.mdpi.com/2072-6694/15/13/3425

Futile surgeries at 10-25%

Pancreatic Ductal Adenocarcinoma [1]NCCN Guidelines

Modality	Primary disease	Preoperative staging/Met detection	Peritoneal	Comments
EUS	YES	NO	NO	Primary disease site. Complementary to CT Not routine staging
CT	YES	MAYBE Accuracy: 70-85%	NO	Staging, restaging and follow up
FDG PET		MAYBE	NO	Added sensitivity for distant mets. Staging and treatment monitoring
MRI		Hepatic Staging YES		Complementary to CT Especially in hepatic staging
[2] Laparoscopy			YES	

1 NCCN Guidelines Version 2.2025, 02/03/2025
2 https://www.mdpi.com/2072-6694/15/13/3425

CA 19-9 a key serum biomarker for disease progression

Futile surgeries at 10-25%

Phase 3- FAPI-GO at a Glance

Trial Name
Using [^{18}F]FAPI PET to Detect Metastatic Disease in patients that have gastric or esophageal cancer (FAPI-GO)

ClinicalTrials.gov ID
NCT07217704

Activation date
Nov 2025, estimated completion of 2 years

Site Info
18 Sites to be activated by mid-2026

Patient Population
Estimated enrollment of 200 Adults with pathologically confirmed gastric, gastroesophageal junction, or esophageal cancer undergoing staging for treatment planning

[^{18}F]FAPI-74
Radioactive diagnostic agent used in PET for detection of Fibroblast Activation Protein (FAP)+ cancer cells

Outcome Measures
Sensitivity and specificity for detection of distant metastatic disease (M1) compared to Standard of Truth (SOT)

Phase 3- FAPI-PRO at a Glance

Trial Name
Using [^{18}F]FAPI PET to Detect Metastatic Disease in patients that have pancreatic ductal adenocarcinoma (PDAC) (FAPI-PRO)

ClinicalTrials.gov ID
NCT07217717

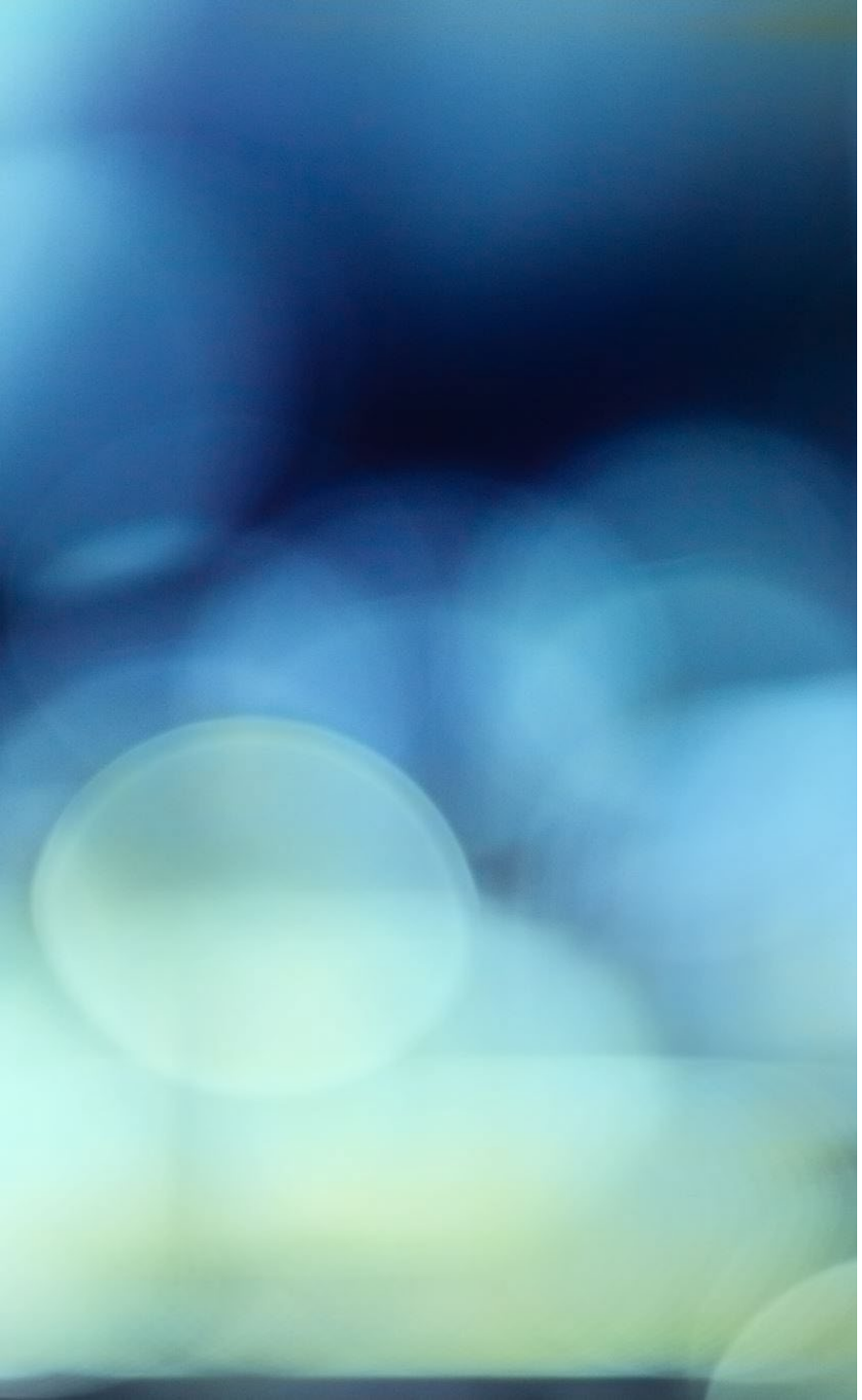
Activation date
Dec 2025, estimated completion of 2 years

Site Info
18 Sites to be activated by mid-2026

Patient Population
Estimated enrollment of 200 Adults with pathologically confirmed PDAC undergoing staging for treatment planning

[^{18}F]FAPI-74
Radioactive diagnostic agent used in PET for detection of Fibroblast Activation Protein (FAP)+ cancer cells

Outcome Measures
Sensitivity and specificity for detection of distant metastatic disease (M1) compared to Standard of Truth (SOT)



Lessons learned and Closing

FAP targeting has tremendous potential in oncologic and non-oncologic disease detection. Currently SOFIE is pursuing gastroesophageal cancers and PDAC.

Care should be taken in identifying performance and potential utility in specific diseases and stages of disease (primary disease, lymph nodes, distant mets, staging, re-staging and treatment monitoring) where current modalities fall short.

Consultation with treating physicians, surgeons and relevant care providers results in critical insights for identification of unmet need and trial design.

Industry Sponsors should consider supply chain and ability to support clinical trial distribution (Phase 2 and Phase 3) along with commercial launch feasibility.

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Thank you