

# SOFIE

From start to clinic

## **FAP1 Clinical Development Updates**

6/12/22

Sherly Mosessian Ph.D

Chief Scientific Officer

SOFIE

[Sherly.Mosessian@sofie.com](mailto:Sherly.Mosessian@sofie.com)

# Advancement drives us. Purpose compels us.



## 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.



## Partnership

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



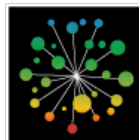
## PET Education

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

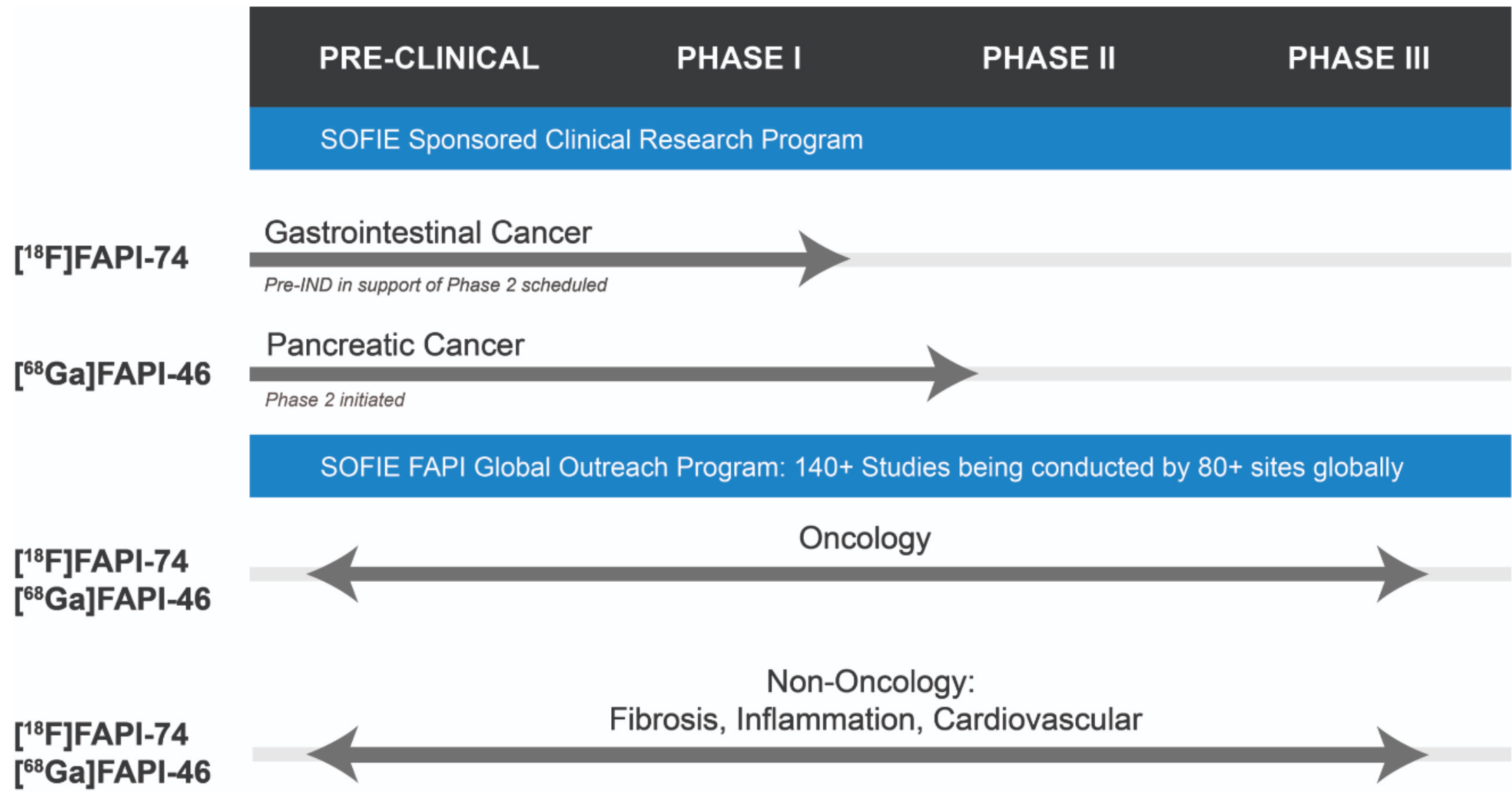


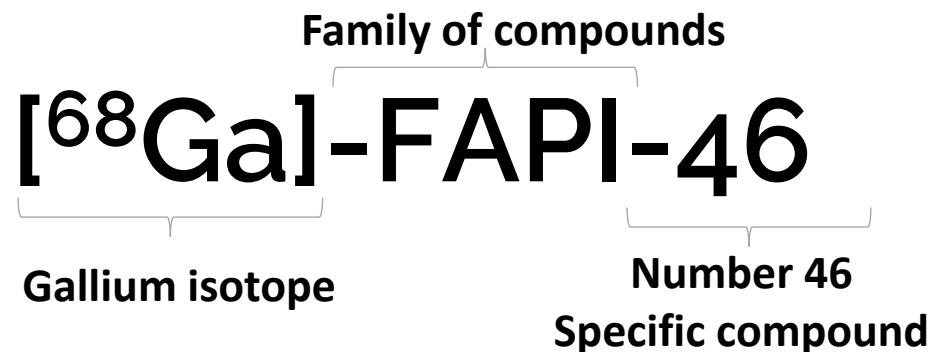
## Our Network

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.

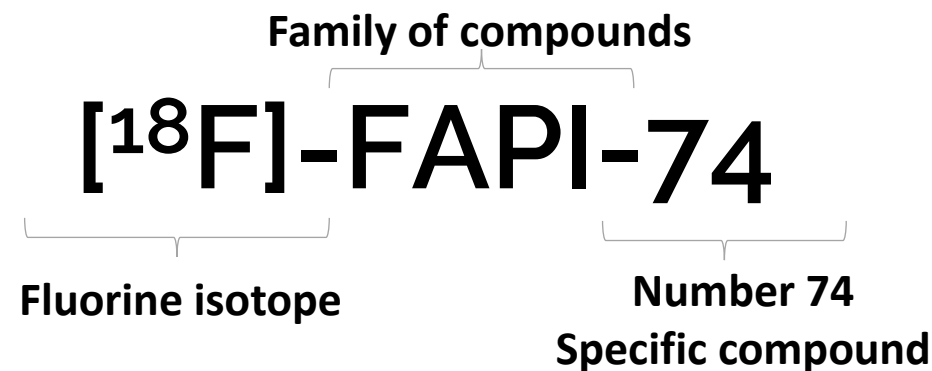


# SOFIE's Product Pipeline





- Lead **gallium** labeled compound
- DOTA chelator in the molecular structure allows coupling of the FAPI molecules for theranostic use
- SOFIE has obtained an **IND** for [<sup>68</sup>Ga]-FAPI-46 for a Phase 2 study
- 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**
- Study launch: **May 2022**
- First site activated: **NYU**



- Lead **Fluorine 18** compound
- Allows for broader applicability of FAP PET through 18-F radiolabeling
  - Established supply chain with higher level of supply capacity with convenience to imaging practices
  - Provides advantage of a longer half life (2 hours)
  - Meeting the capacity to support larger studies with high patient throughput
- **Automated synthesis** consumables available through Trasis for MiniAIO and AIO
- Pre-IND meeting scheduled with FDA for **July 2022**
- IND enabling data completed





## SOFIE's FAPI Global Outreach Program

- 34 Countries
- 140+ research studies
- Studies include: Chemistry, pre-clinical, clinical, oncology and non-oncology
- 80+ unique institutions
- Compounds: [ $^{18}\text{F}$ ]-FAPI-74 and [ $^{68}\text{Ga}$ ]-FAPI-46

# 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



# THANK YOU!

Questions? Please reach out to  
[sherly.mosessian@SOFIE.com](mailto:sherly.mosessian@SOFIE.com)

