

Promoting Early Drug Development in Spain

Challenges and Advantages for the Cooperative Groups

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Vall d'Hebron University Hospital and SOLTI

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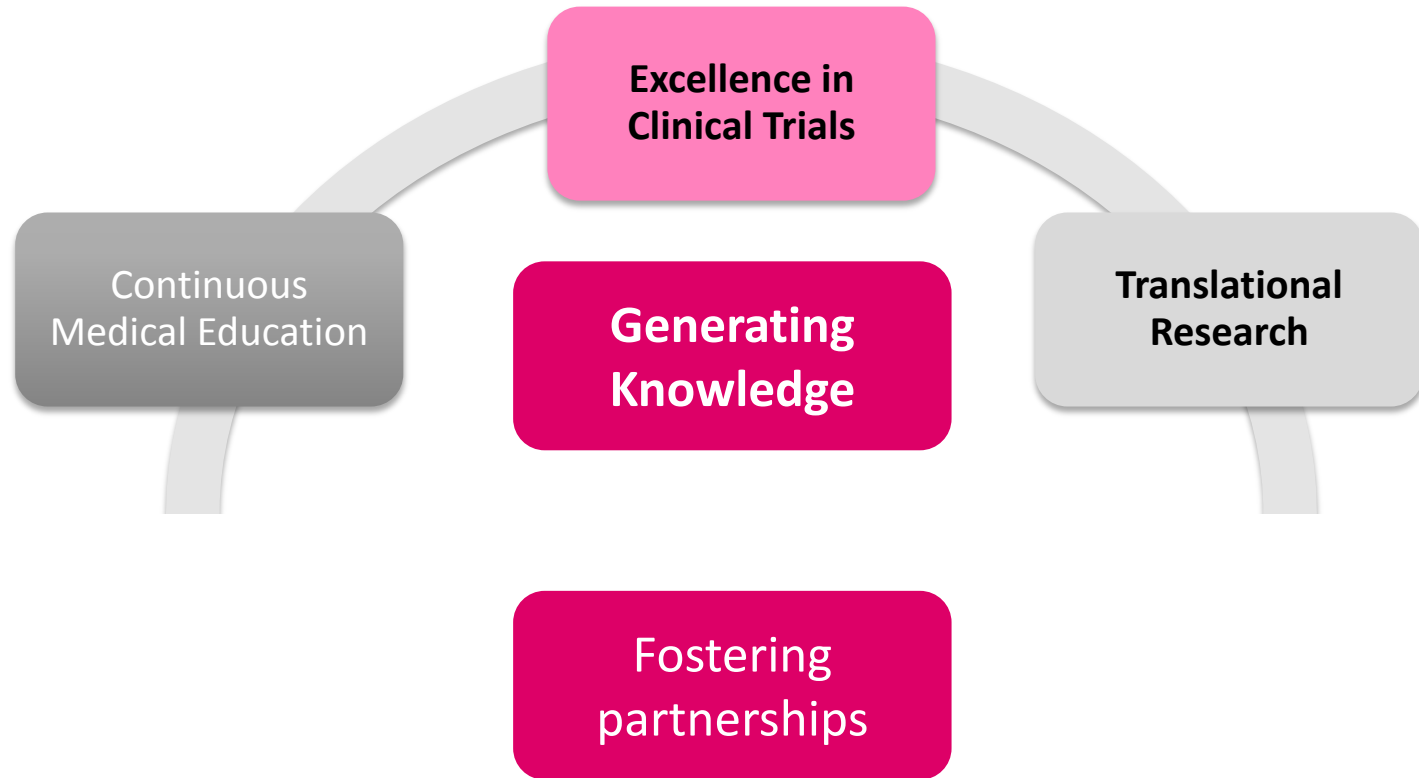
How can Cooperative Groups improve Early Drug Development?

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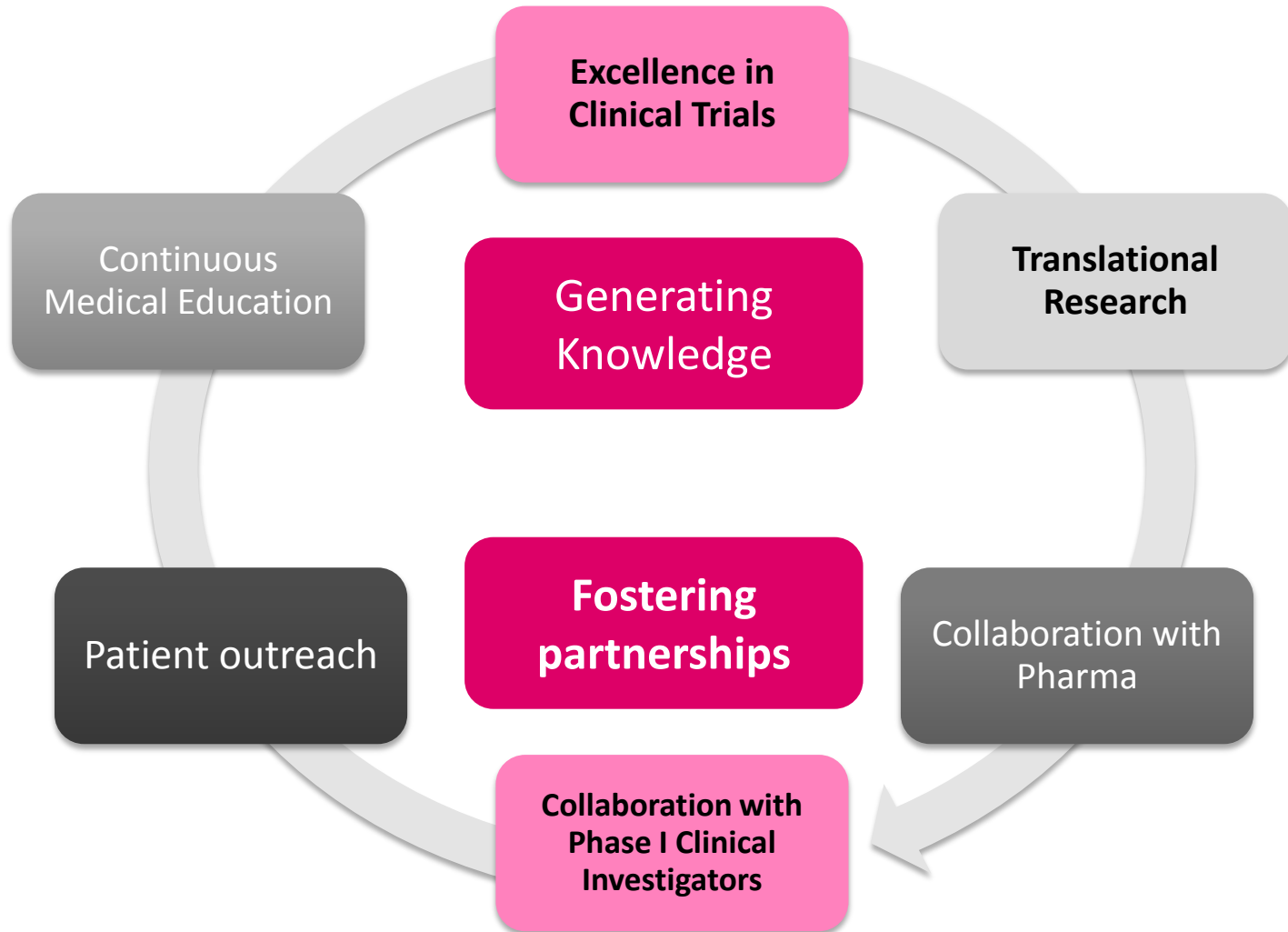
**Generating
Knowledge**

**Fostering
partnerships**

How can Cooperative Groups improve Early Drug Development?



How can Cooperative Groups improve Early Drug Development?



SOLTI is an Academic research organization founded in 1995, focused on breast cancer clinical research

- Internationally **recognized investigators** generating innovative clinical trial designs → Neoadjuvant model / Biosamples acquisition and analysis
- **Network of leading hospitals** in Spain, Portugal, France, and Italy with high recruitment capacity
- **Dedicated Headquarters Office** that supports all activities, including clinical operations
- **Pharmaceutical partner** in clinical development and life cycle management of anticancer agents for breast cancer

SOLTI's mission

- 🕒 To conduct cutting-edge clinical research, in particular with novel therapeutics and incorporating translational science, aimed at reducing the morbidity and mortality of breast cancer
- 🕒 To foster collaboration in international networks
- 🕒 To promote excellence in breast cancer care among our members

Executive Board

General Assembly

Scientific Committee

Focus on proof of concept and translational research

Currently participating in **30 clinical trials**, most of them international,
focused in neoadjuvant setting

- 🕒 Sponsored by SOLTI: **9**
- 🕒 In collaboration with pharmaceutical sponsors: **11**
- 🕒 In collaboration with other academic groups: **10**
- 🕒 Focus on proof of concept, translational studies
- 🕒 New study proposals under discussion: **10**

Additionally, leading **ÁGATA**, the first Molecular Screening
Program in Spain



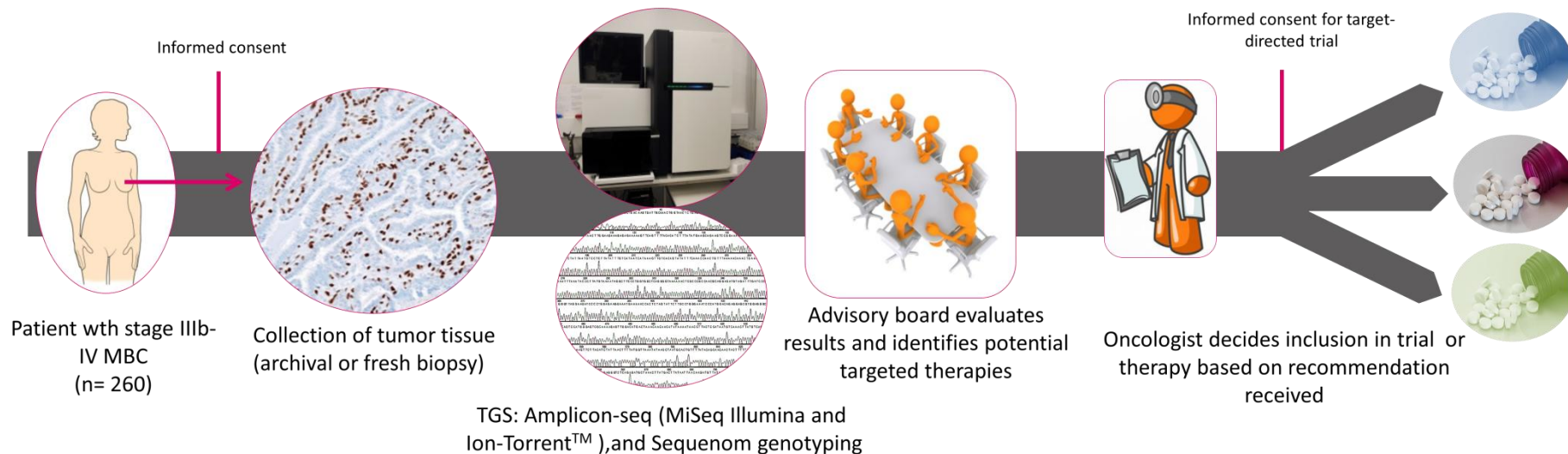
Programa SOLTI de cribado genómico

MISSION

Provide a **molecular screening program** to breast cancer patients inside SOLTI network that contributes to our **knowledge about breast cancer tumor biology** and **facilitates the access of these patients to clinical trial** with target therapy tailoring their treatment
(personalized medicine)

STUDY DESIGN

- Target accrual= 260 patients stage IIIB-IV any line of treatment
- 8 participating sites
- 3 central laboratories





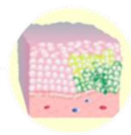
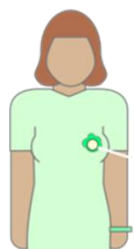
Programa SOLTÍ de cribado genómico

PARTICIPATING SITES

Samples collection

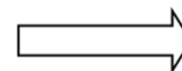
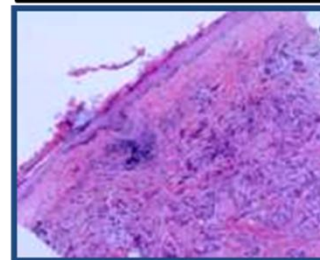
Samples collection +
analysis



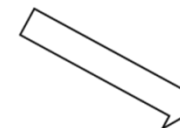
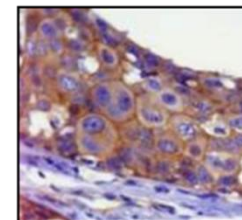


MOLECULAR PATHOLOGY LAB

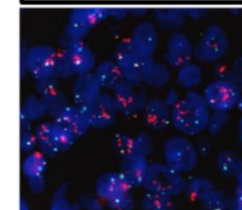
H&E QC



IHC/IF

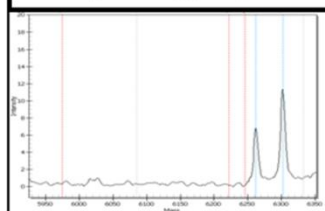


FISH



CANCER GENOMICS LAB

Sequenom
genotyping



NGS



Sequenom: 288
mutations in 24
oncogenes

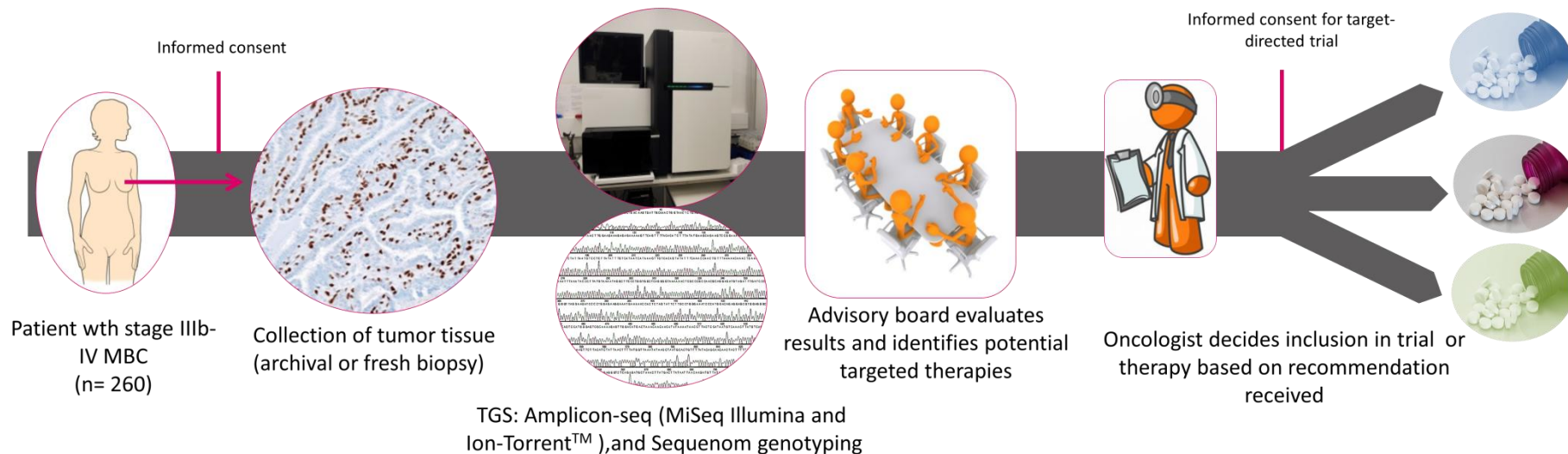
Amplicon-seq: 3000
mutations en 57
genes

Oncopanel

ABL1	FGFR1	KIT	PIK3R1
AKT1	FGFR2	KRAS	PIK3R5
AKT2	FGFR3	MAG	PTEN
AKT3	FGFR4	MAP2K1	RB1
APC	FLI3	MET	RET
BRAF	GATA1	MLH1	RUNX1
CDH1	GNA11	MPL	SMAD4
CDKN2A	GNAQ	MSH6	SMARCB1
CSF1R	GNAS	MYC	SRC
CTNNB1	GSK3B	NF2	STK11
EGFR	HRAS	NOTCH1	TP53
ERBB2	IDH1	NOTCH4	VHL
ERBB3	IDH2	NRAS	
ESR1	JAK1	PDGFRA	
FBXW7	JAK3	PIK3CA	

STUDY DESIGN

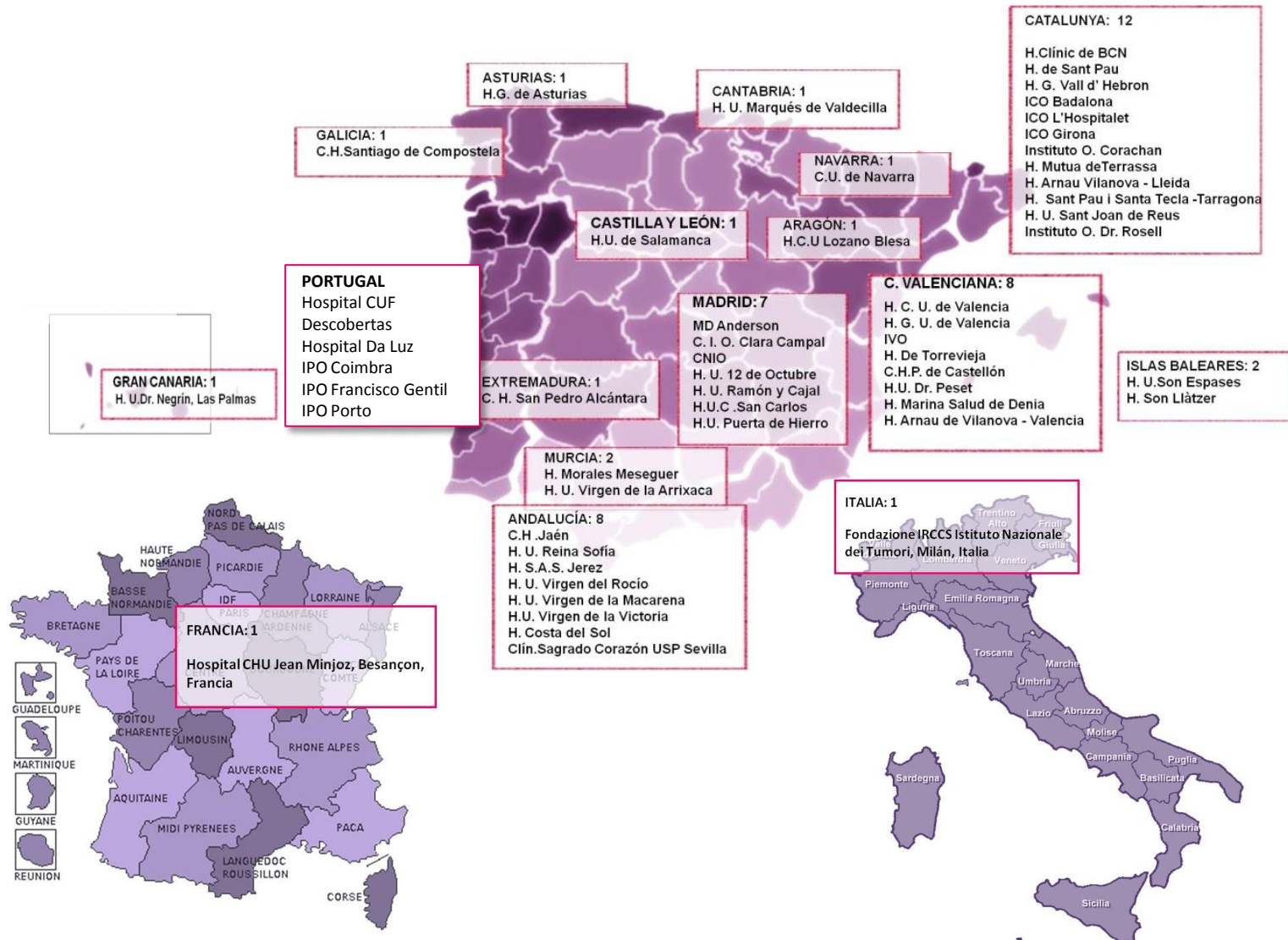
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Fostering
partnerships

SOLTI network

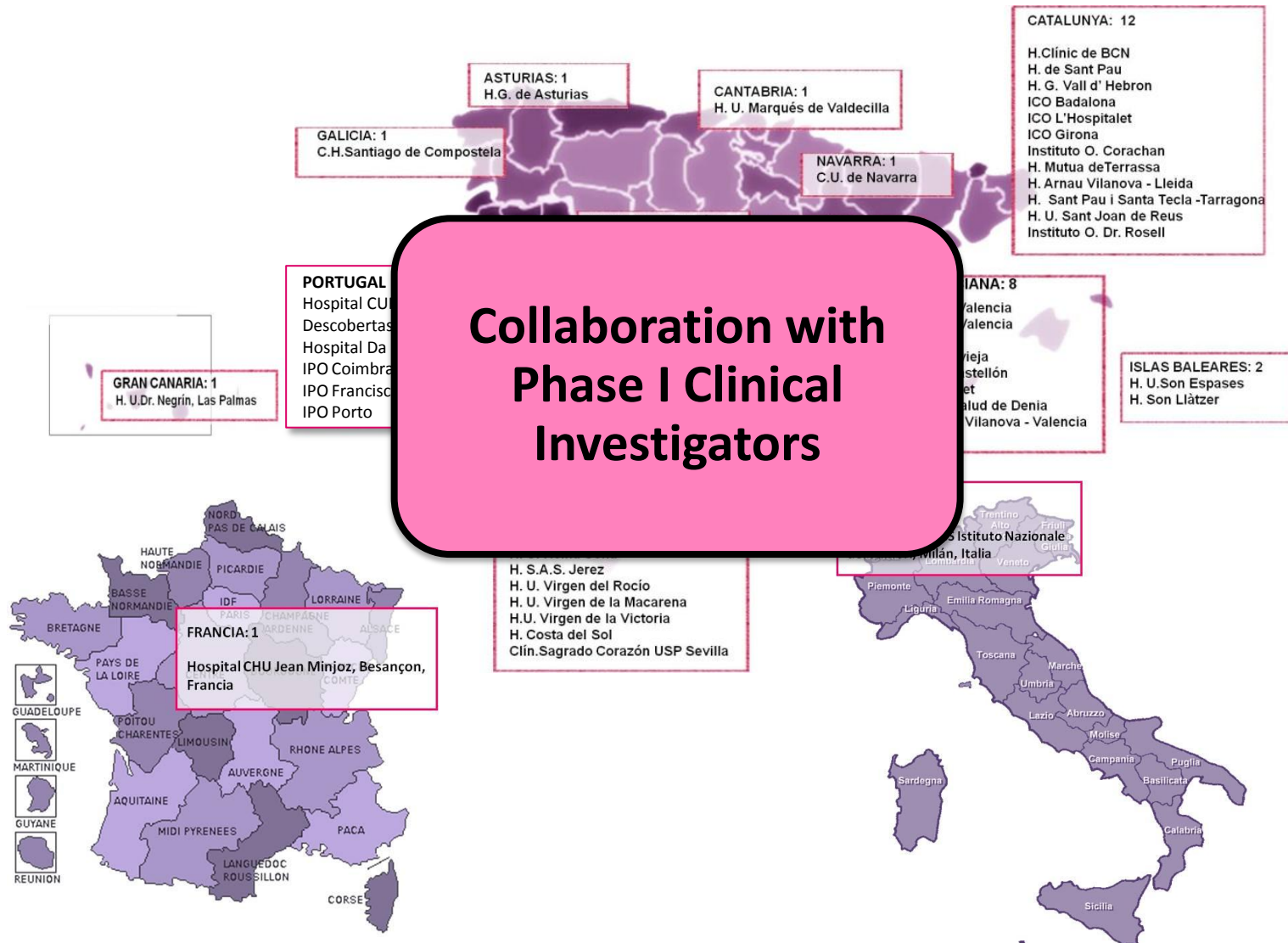
Top hospitals with high recruitment capacity



Fostering
partnerships

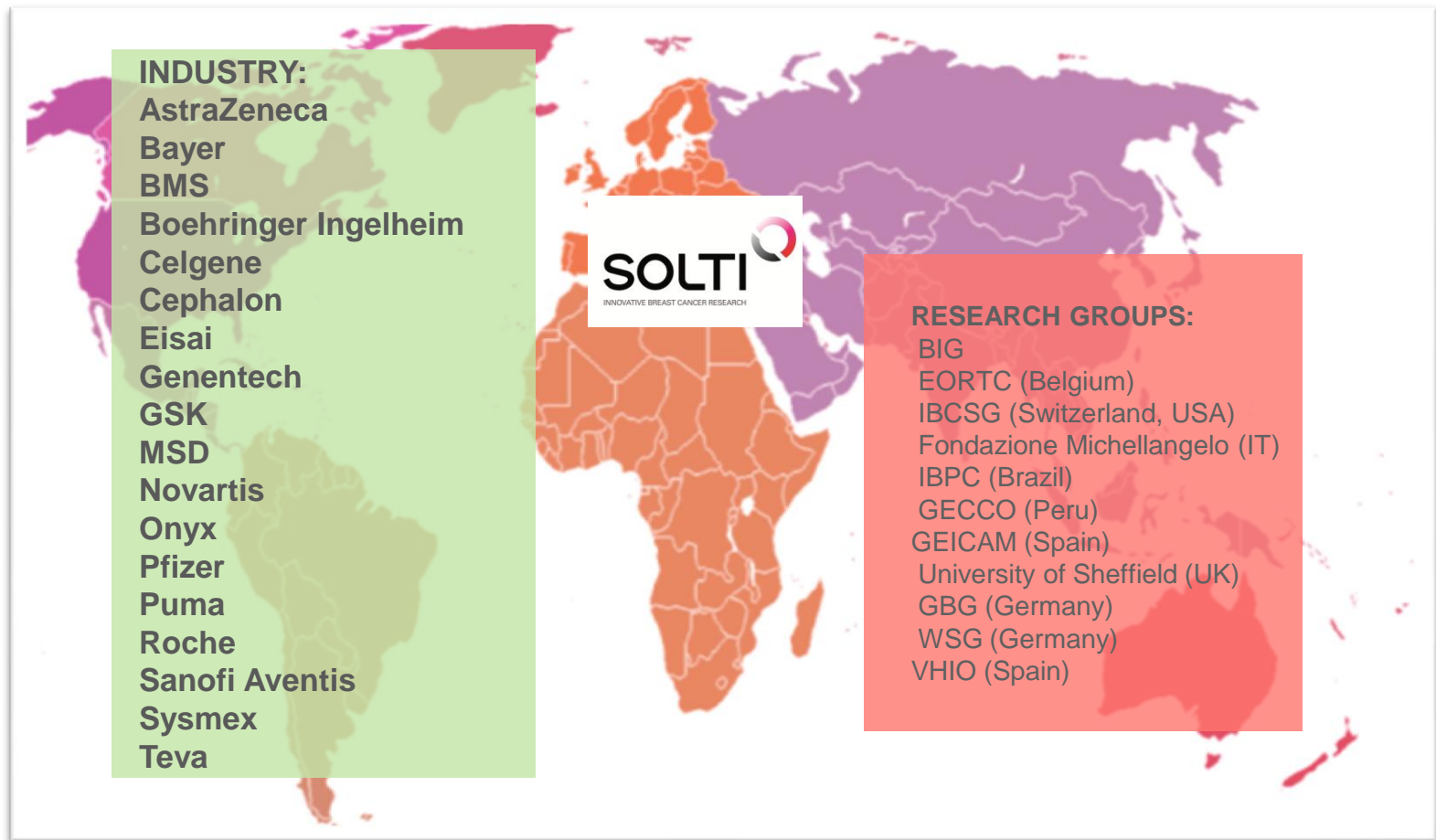
SOLTI network

Top hospitals with high recruitment capacity

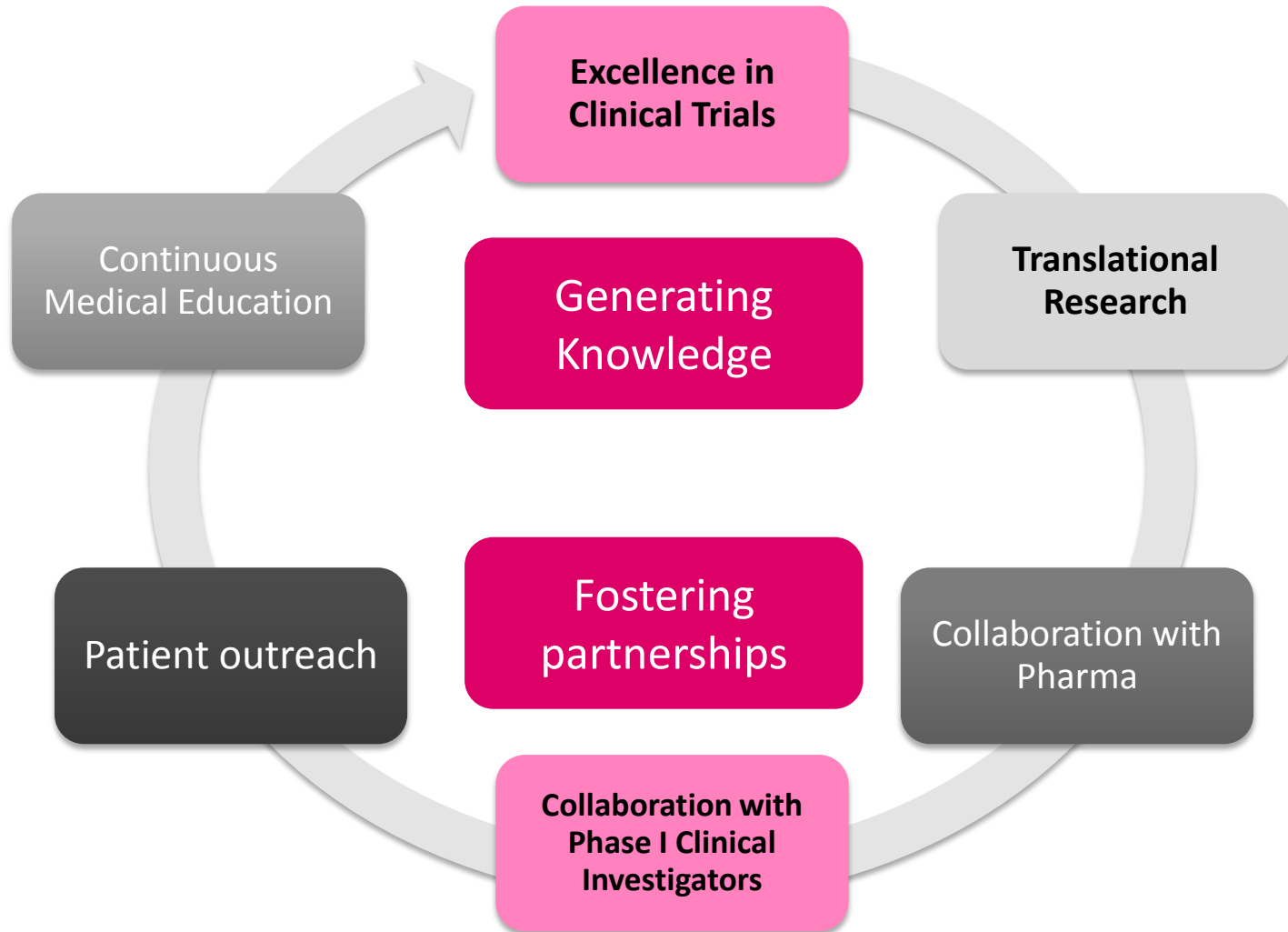


Fostering
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Collaborations around the world



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THANK YOU

