

# ÁGATA molecular screening program: Implementing precision medicine in patients with advanced breast cancer in Spain

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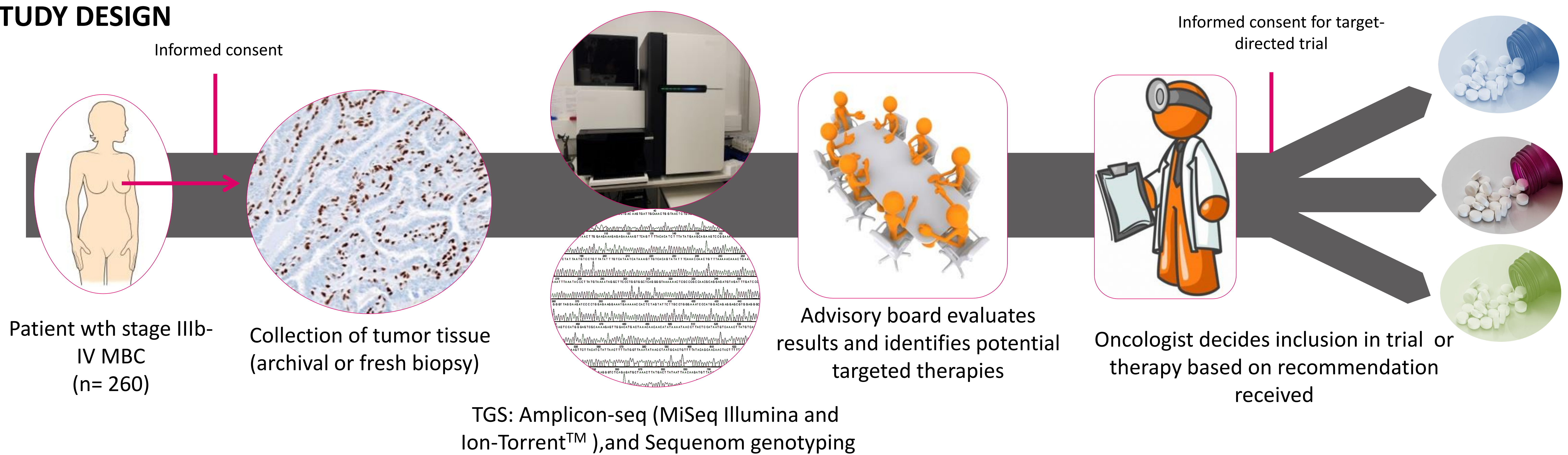
## BACKGROUND

Metastatic breast cancer continues to be a major cause of cancer death among women globally. In recent years, a better understanding of tumor biology, namely, many molecular drivers of the disease, and the availability of high throughput technologies, has enabled the emergence of precision medicine bringing new expectations<sup>1,2</sup>. Furthermore, the shift from single-biomarker focus to the simultaneous examination of large numbers of alterations in order to optimize drug development has resulted in the rise of molecular screening programs worldwide<sup>3</sup>. In Spain, however, only a few institutions have implemented such initiatives. With this in mind, SOLTI, as collaborative network, aims to expand the access to enabling technologies and expertise to perform molecular screening of patients and facilitate their access to clinical trials with novel targeted agents.

## OBJECTIVES

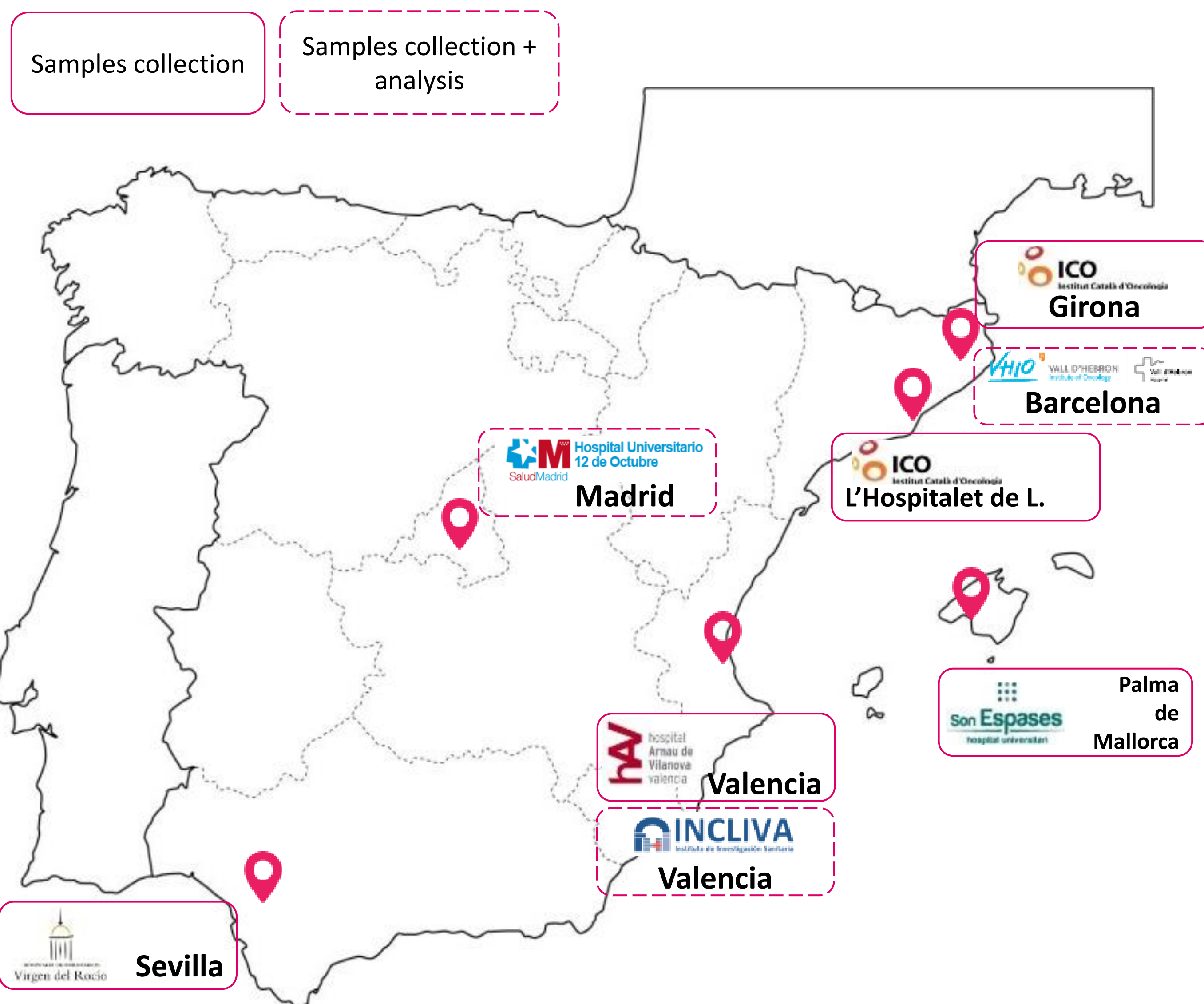
During this pilot stage, our primary objective is to determine the program's effectiveness to recommend clinical trials to patients based on their molecular profile. Additional aims are to identify technical and logistical barriers to the implementation of a nationwide program, to describe the genomic profiles of the tumors, and to assess patient outcomes.

## STUDY DESIGN



## PARTICIPATING SITES

Samples collection and laboratories

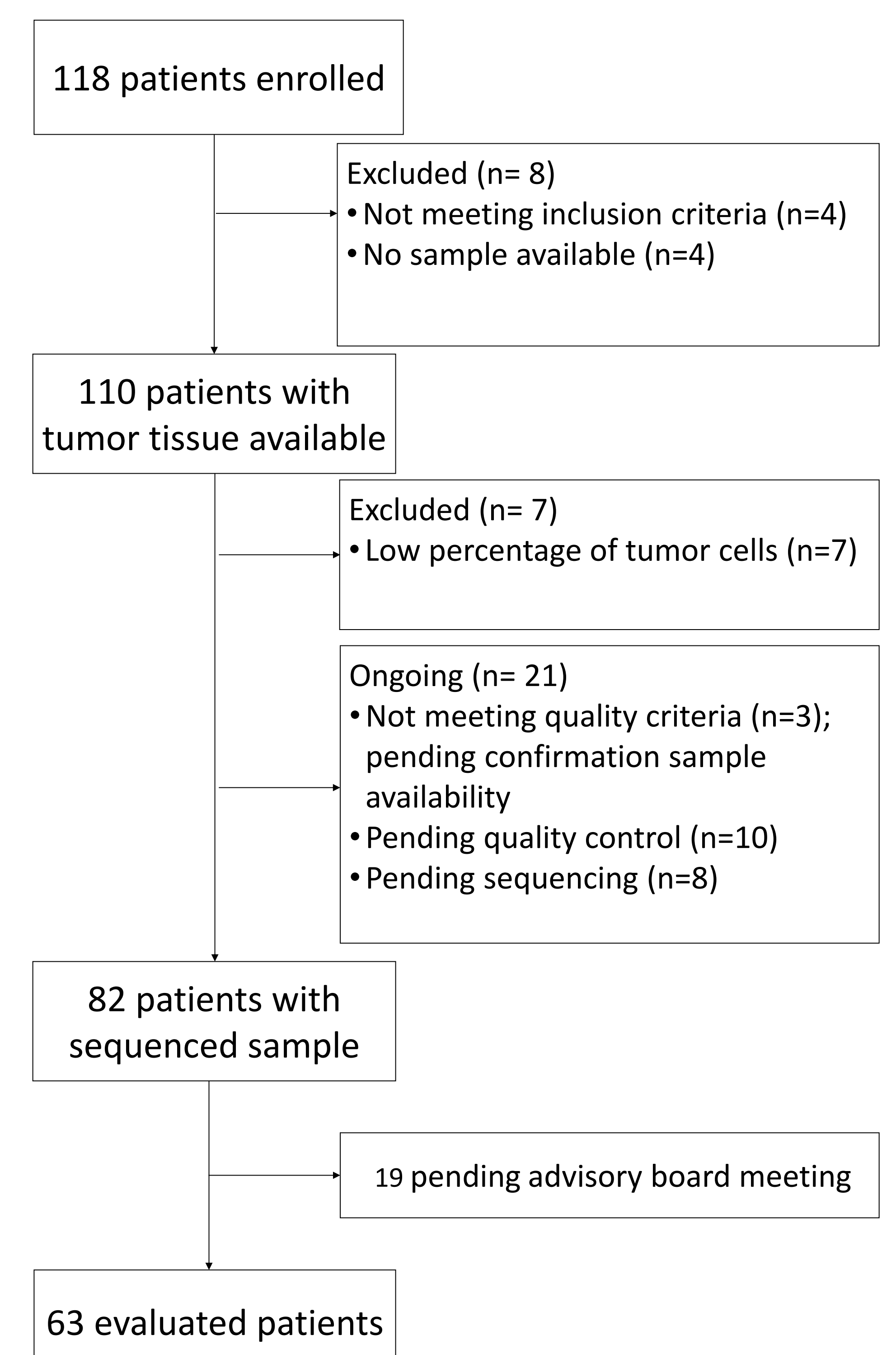


## PANEL OF GENES

ABL1	FBXW7	JAK3	PDGFRA
AKT1	FGFR1	KIT	PIK3CA
AKT2	FGFR2	KRAS	PIK3R1
AKT3	FGFR3	MAG	PIK3R5
APC	FLT3	MAP2K1	PTEN
BRAF	GATA1	MET	RB1
CDH1	GNA11	MLH1	RET
CDKN2A	GNAQ	MPL	RUNX1
CSF1R	GNAS	MSH6	SMAD4
CTNNB1	GSK3B	MYC	SMARCB1
EGFR	HRAS	NF2	SRC
ERBB2	IDH1	NOTCH1	STK11
ERBB3	IDH2	NOTCH4	TP53
ESR1	JAK1	NRAS	VHL

## STATUS

AGATA is the first multi-institutional molecular screening program ever implemented in Spain. Patient recruitment started in October 2014 and is expected to conclude in 30 months. On August 1<sup>st</sup> 2015 the first interim analysis was completed:



## FUTURE PERSPECTIVES

Upon completion of the pilot stage, transcriptomic and proteomic analysis will be performed. We plan to expand the network of hospitals and laboratories following the evaluation of the feasibility of the program.

## ACKNOWLEDGEMENTS

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## REFERENCES

- Hansen AR, Bedard PL. Clinical application of high-throughput genomic technologies for treatment selection in breast cancer. *Breast Cancer Res.* 2013 Oct 18;15(5):R97
- Ellis MJ, et al. Tine BA, Hoog J, Goiffon RJ, Goldstein TC. Whole-genome analysis informs breast cancer response to aromatase inhibition. *Nature* 2012, 486:353–360.
- André F, et al. Comparative genomic hybridization array and DNA sequencing to direct treatment of metastatic breast cancer: a multicenter prospective trial (SAFIR01/UNICANCER)