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- **Honoraria:** AstraZeneca
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# BRIDGE: Biopsy-based Recurrence score to Improve Decision-making & Guide adjuvant thErapy

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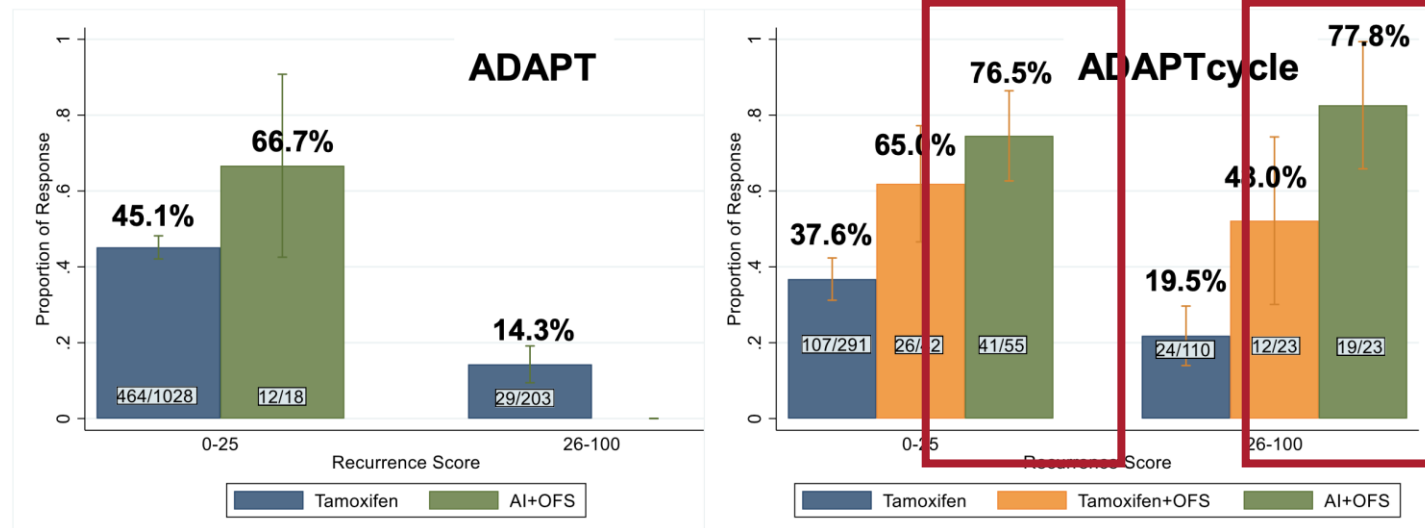
**Steering Committee:** Prof.ssa Lucia Del Mastro, Prof. Michelino De Laurentiis, Prof.ssa Alessandra Fabi, Prof. Fabio Puglisi, Dott. Saverio Cinieri

# Background - I

- Based on gene expression assay (GEA) results, **CT can safely be omitted** in postmenopausal pts with 0-3 LN and in N0 premenopausal pts with low-risk GEA results (TAILORx, RxPONDER, MINDACT)<sup>1-3</sup>
- **OncotypeDx<sup>®</sup> (ODX) is the only test with level I,A evidence** for clinical decision-making according to international guidelines<sup>4</sup>
- Currently, **ODX in Italy is only reimbursed on surgical specimen** to guide clinical decision-making on adjuvant chemotherapy administration
- Previous data published in the literature show:
  - **high success rate** of informative **ODX** results on core-needle biopsy (CNB) samples (94.5% CNB vs 97.3%)<sup>5</sup>
  - **nearly identical RS distribution and single-gene metrics** between CNB and surgical samples<sup>5</sup>
  - **high correlation of microarray-based RS** ( $r = 0.82-0.91$ )<sup>6</sup>

# Background - II

- **Dynamic Ki67 response** to short preoperative endocrine therapy (ET) is associated with endocrine responsiveness and favorable patient outcomes (POETIC)<sup>1</sup>
- WSG-ADAPT<sup>2</sup> demonstrated that **endocrine response assessment** allows CT de-escalation without compromising outcomes (5-year dDFS 97%)
- WSG-ADAPT<sup>2</sup> and WSG-ADAPTCycle<sup>4</sup> demonstrated that the **proportion of patients achieving an endocrine response is strictly dependent on the type of ET administered and not influenced by RS on CNB**



# Current gaps

- Currently, **ODX<sup>®</sup>** in Italy is not reimbursed on core needle biopsies
- Unavailability of ODX in this context
  - **limits the adoption of perioperative ET to assess endocrine-responsiveness** and thus de-escalate chemotherapy
  - **does not allow accurate risk stratification** among patients participating in novel trials (e.g. SERDs)
- **No previous study has evaluated changes in RS after short ET treatment course and correlation with ET responsiveness as defined by reduction in Ki67**
- Use of GEA, including **ODX**, is **currently not recommended among premenopausal patients with N1 disease** although in the context of the RxPonder trial several question whether the use of optimal adjuvant ET could be a substitute for adjuvant chemotherapy

# Study proposal – BRIDGE: Biopsy-based Recurrence score to Improve Decision-making & Guide adjuvant thErapy

## Rationale

- **Early RS from core biopsy (CNB) could:**
  - Shorten time to definitive adjuvant plan.
  - Allow a **4-week endocrine therapy (ET) window** to document endocrine sensitivity.
  - Provide **paired RS (pre/post)** and **Ki-67 dynamics** data missing from the literature.
- **Reimbursement issue in Italy:** need real-world data that performing OncotypeDx<sup>®</sup> on CNB is feasible, effective, and clinically meaningful.
- **RS + ET response** could help **tailor therapy** and reduce unnecessary chemotherapy.

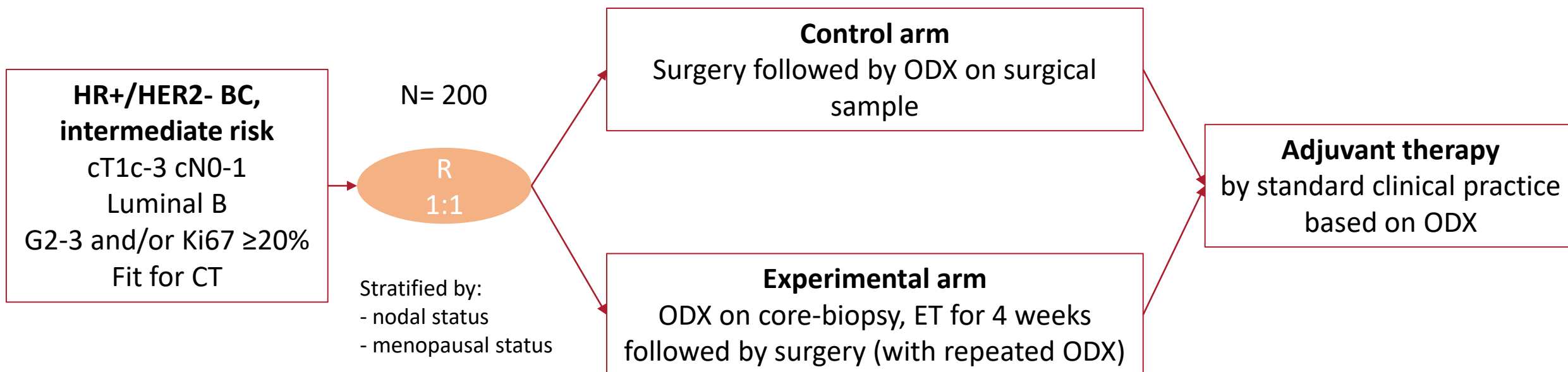
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## Study objectives

- **Primary:** Reduce **time to definitive adjuvant therapy decision** by delivering RS **before surgery**.
- **Key secondary:**
  - Evaluate **success rate** and **turn-around time** for ODX on CNB in the Italian system.
  - Correlate **ET response (Ki-67 drop)** with **RS pre and post ET**.
- **Exploratory:** Describe treatment choice and outcomes of **premenopausal N0/N1** patients with endocrine response by Ki-67 and may **avoid chemotherapy**.

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## Study design



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## Open discussion

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