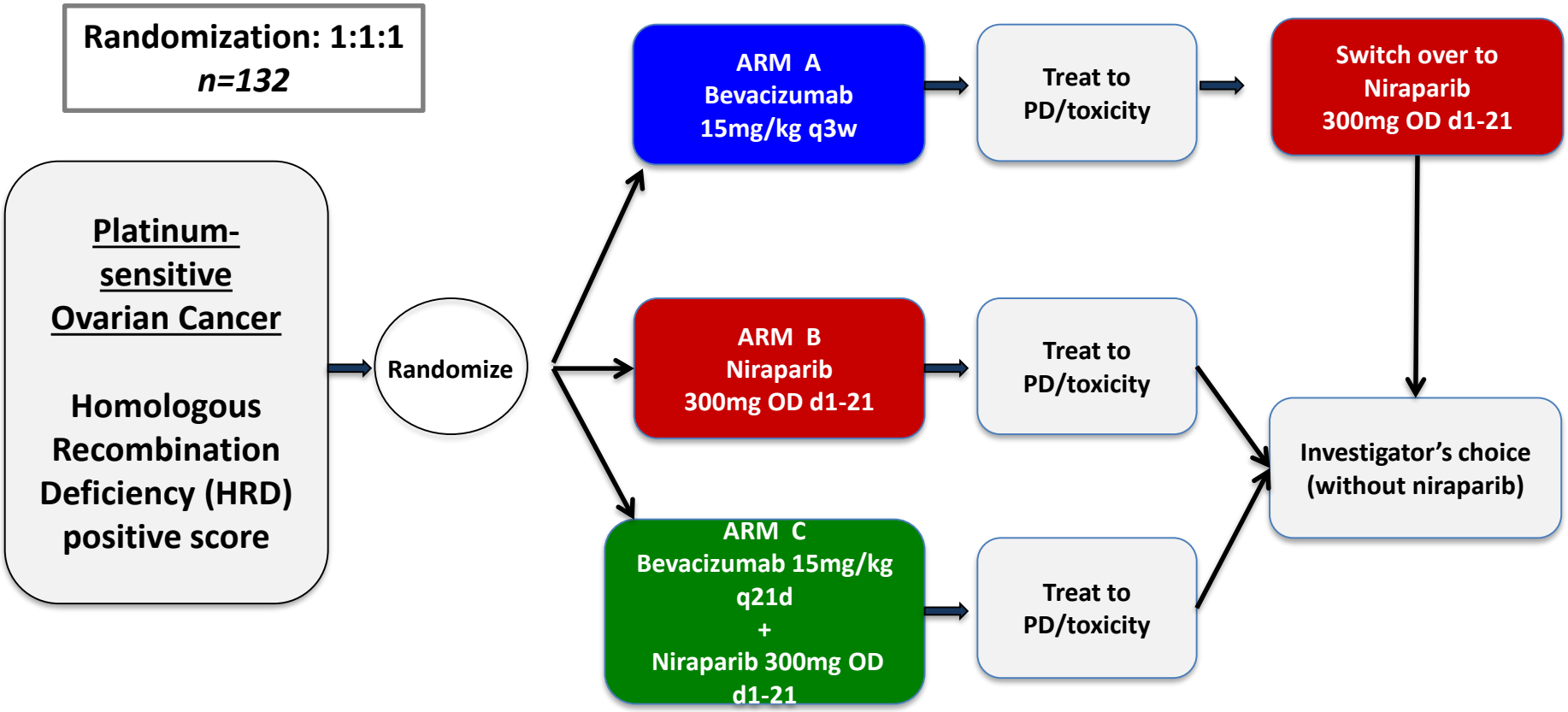
ENGOT-OV24-NSGO/AVANOVA

Phase 2



Sponsor: NSGO
Project Manager: Louisa Boufercha
Statistitian: DePont Christensen
PI: Mirza

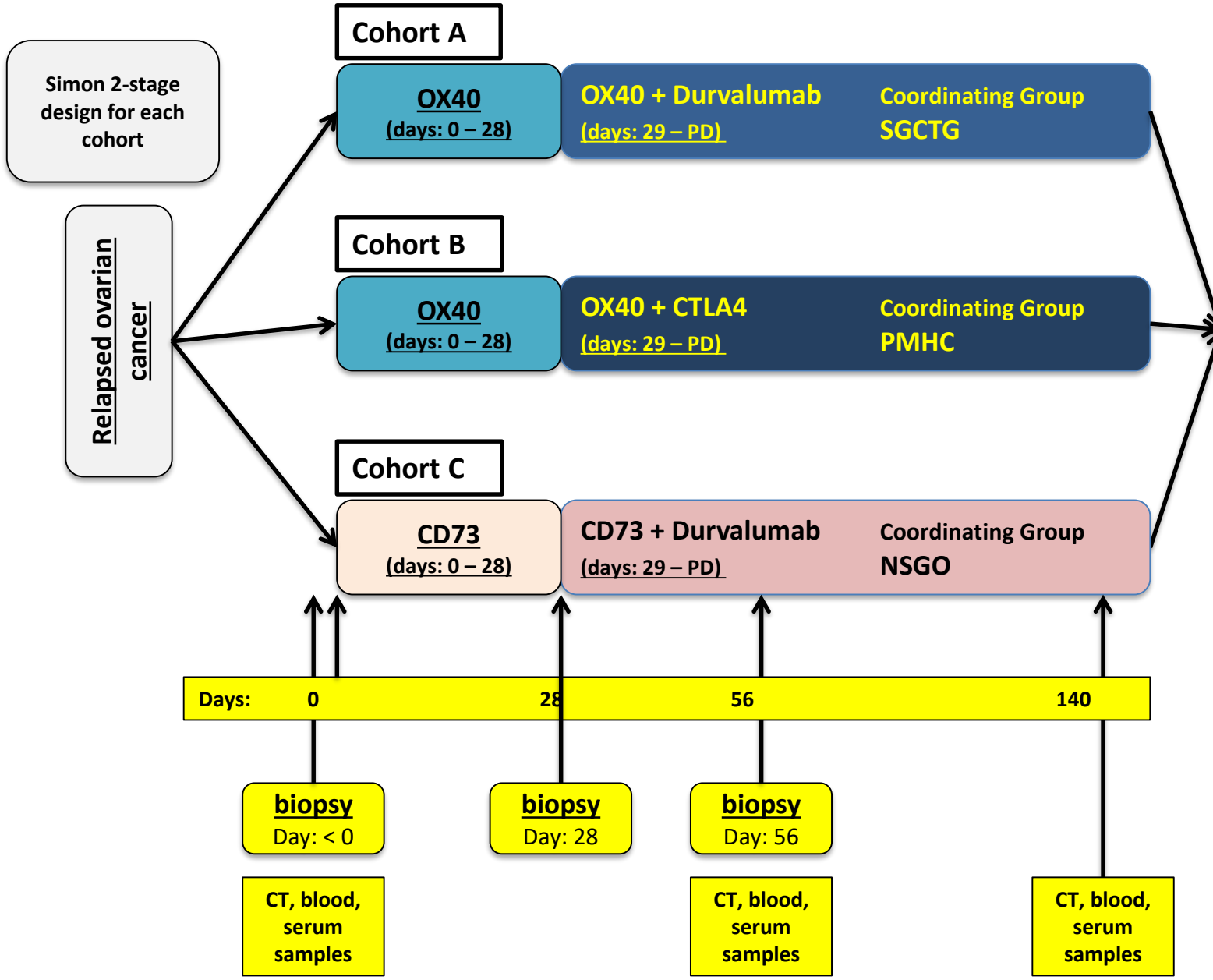
Stratifications

- BRCA status: BRCA mutated vs. non-carrier
- Prior receipt of anti-angiogenic therapy (yes/no)
- Prior lines of therapy: 1-3 vs > 3 lines

ENGOT-OV24-NSGO/AVANOVA (Phase 2) - Trial Status

Country	Sites	PI	Submission status	SIV	Randomized
DK	Rigshospitalet	**Mansoor R. Mirza (NC)**	• CA: Approved: 18.12.2015 • EC: Approved: 01.03.2016	03.12.2015	3
	Herlev	Trine Juhler-Nøttrup		30.03.2015	2
	Odense	Jørn Herrstedt		08.03.2016	-
	Aarhus	Ranva Hassel		19.08.2016	-
	Aalborg	Bente Lund		16.12.2015	3
FI	Tampere	**Johanna Mäenpää (NC)**	• CA: Approved: 19.07.2016 • EC: Approved: 06.06.2016	30.09.2016	-
	Kuopio	Maarit Anttila		TBD	-
	Turku	Sakari Hietanen		TBD	-
NO	Haukeland	**Line Bjørge (NC)**	• CA: Approved: 29.09.2016 • EC: Approved: Oct 2016	TBD	-
	Stavanger	Bent Fiane		TBD	-
SE	Lund	**Susanne Malander (NC)**	• CA: Approved 22.04.2016 • EC: Approved: 22.03.2016	16.09.2016	-
	Linköping	Per Rosenberg		26.09.2016	-
	Sahlgrenska	Maria Dimoula		16.09.2016 (web-based) On site monitoring visit pending	-
	Uppsala	Hanna Dahlstrand		16.09.2016 (web-based) On-site monitoring visit: 11.11.2016 (Planned)	-
US	MGH	**Michael Birrer (NC)**	• Hard copies were submitted by GSO to FDA and were received the 09.09.2016. • Re-submission to FDA done 20.09.2016. • The 16.09.2016 Myriad submitted the risk determination letter and the acknowledgement letter to FDA. It was received on 19.09.2016. • Reply with comments received from FDA on 05.10.2016.The IND was clinically reviewed and following a response were send to FDA to answer their criticisms. Currently waiting for a response from FDA.	TBD	-
	Huntsman Cancer Institute	Theresa Werner		TBD	-
Total					**8**

NSGO-OV-UMB1: A Phase 2 Umbrella Trial in Recurrent Ovarian Cancer



mansoor@rh.regionh.dk