192P Population sizes of patients (pts) with node negative (N0), HR+, HER2− primary breast cancer (BC), using standard and TAILORx 21-gene recurrence score (RS) cut-off values (COV)

J-U. Blohmer[1], M. Verrill[2], C. Fortmann[3], C. Chao[3], J. Gligorov[4]

[1]Klinik für Gynäkologie mit Brustzentrum, Charité-Universitätsmedizin Berlin, Berlin, Germany, [2]Northern Institute for Cancer Research, Newcastle University, Newcastle Upon Tyne, UK, [3]Medical Affairs, Genomic Health, Inc., Redwood City, CA, USA, [4]Department of Medical Oncology, APHP, Hôpital Tenon, Paris, France

Background: Whether to use adjuvant chemotherapy (CT) is a crucial decision for pts with HR+, HER2− primary BC. The 21-gene Recurrence Score® (RS) assay is validated to predict adjuvant CT benefit and risk of recurrence, using standard RS COV of < 18, 18-30, and ≥31. Of ~59K N0/N1 pts from two real-world registries, those with RS < 18 (>50% of total) largely treated without CT had favorable 5-y outcomes. The prospective TAILORx and PlanB clinical trials showed excellent 5-y outcomes for RS < 11 and RS ≤ 11 subgroups, respectively, treated without CT. The AJCC now recommends use of RS < 11 to down-stage to 1A. The capacity to generalize regional study outcomes globally requires first that RS subgroup sizes are geographically consistent. Here, we analyze RS subgroup sizes across geographical regions using standard and TAILORx COV.

Methods: Pts with N0, HR+, HER− primary BC and RS results from 2004 to April 2017 were included (data from Genomic Health). Subgroup sizes were determined for RS < 11, 11-17, 18-25, 26-30, and ≥31 in the US, Germany, the UK, France, and the rest of the world (RoW).

Results: Of 609,247 unique RS records analyzed, 513,035 were from the US, 29,248 from EU countries, and 66,964 from RoW. The relative population sizes of RS subgroups were highly consistent across geographical regions. Deviations in percentages for each RS range were within ±3% (Table). Across all regions, >50% of pts had RS < 18.

Conclusions: Our analysis revealed highly consistent RS subgroup classifications across geographic regions, mirroring observations from registry studies, suggesting that tumor biology as characterized by RS results does not vary by geography. Our findings therefore support the generalizability of outcomes-study results using standard or custom COV across geographic regions.

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Table: 192P

	US (N = 513035)		UK (N = 10154)		Germany (N = 14856)		France (N = 4238)		RoW (N = 66964)		All regions (N = 609247)	
RS group	n	%	n	%	n	%	n	%	n	%	n	%
<11	109396	21	1775	17	2714	18	818	19	12989	19	127692	21
11-17	178070	35	3171	31	5295	36	1426	34	23499	35	211461	35
18-25	135783	26	2844	28	4207	28	1185	28	18622	28	162641	27
26-30	35512	7	848	8	1161	8	393	9	5000	7	42914	7
≥31	54274	11	1516	15	1479	10	416	10	6854	10	64539	11