

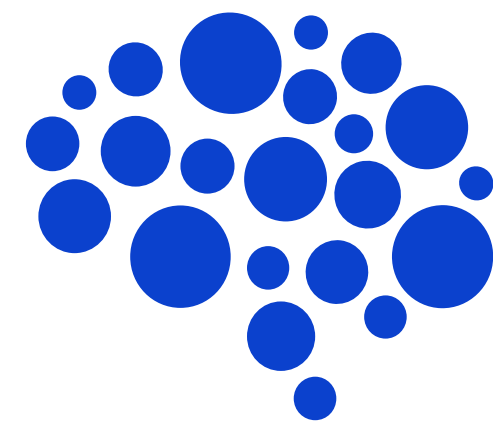
A low-burden cognitive prescreening protocol for enhanced diversity and recruitment in Roche’s Alzheimer’s disease clinical trials



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What does this mean for the Alzheimer’s disease (AD) community?

- The BP45085 pre-screening pilot demonstrates an operational pathway to lower the entry barrier for clinical trials, expanding access across diverse populations in the US, Spain and Poland
- Deploying low-burden pre-screening protocols alongside targeted community outreach mitigates historical structural barriers to clinical trial enrolment
- Strategic site selection and regional collaborations successfully diversify the screening funnel, enhancing the real-world representativeness of clinical trial populations

Background

- AD clinical trials face persistent recruitment barriers, characterised by high screen-failure rates and a critical lack of participant diversity across racial, ethnic and socioeconomic strata^{1,2}
- Enrolling in complex interventional studies requires extensive, high-burden screening evaluation that results in high rates of late-stage ineligibility
- These recruitment constraints broad trial access, limit the generalisability of clinical outcomes and slow the development of scalable disease-modifying therapies
- This pilot study evaluated the utility of a low-burden, community-accessible pre-screening protocol to identify and characterise individuals potentially eligible for Roche interventional studies in AD

Methodology

Study design and participants

- This multi-centre, international pilot study evaluated 31 global investigator sites (US: n=12; Spain: n=10; Poland: n=9) between July 2024 and March 2025
- Participants were aged 60–85 years
- 1,818 participants were enrolled, distributed across the US (n=1,216), Spain (n=356) and Poland (n=247)

Assessments

- Demographic profile: Race, ethnicity, educational attainment
- Collection of routine medical and medication history (including family history of AD)
- Cognitive assessments: Mini-Mental State Examination (MMSE) and Clinical Dementia Rating (CDR [optional])

Acknowledgements

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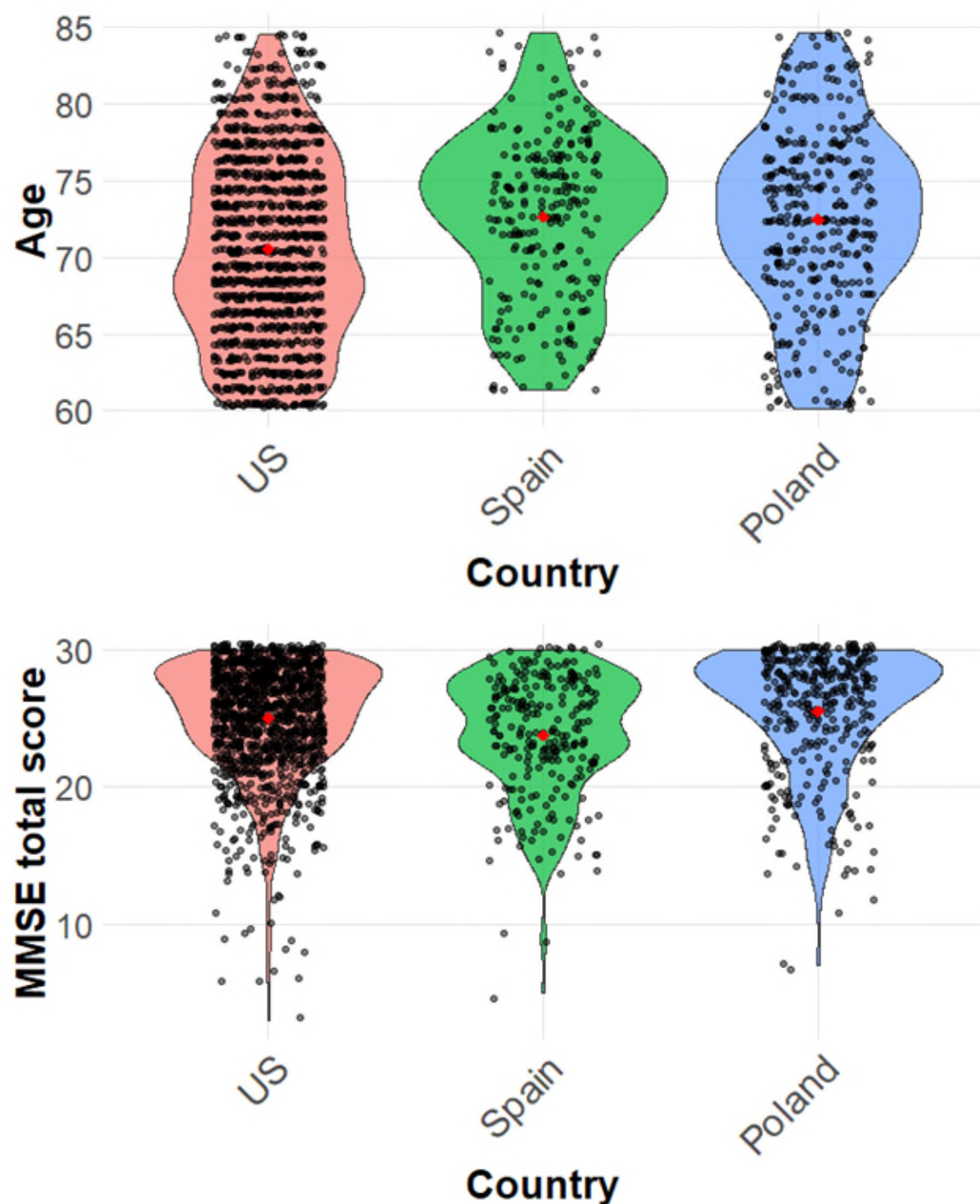
Results

Table 1. Demographic and clinical characteristics.

Demographic and clinical characteristics	1,818 participants
Diagnosis status	
No AD diagnosis	71.7% (n=1,304)
Cognitively unimpaired at risk of AD	3.7% (n=68)
MCI due to AD	14.5% (n=264)
AD dementia	9.8% (n=179)
Age (mean [SD], range, years)	71.2 ± 6.0 60–84
Sex	
Male	34.2% (n=621)
Female	65.8% (n=1,197)
Race	
White	70.7% (n=1,286)
Black	22.1% (n=402)
Asian	2.8% (n=50)
Other*	4.4% (n=80)
Ethnicity	
Hispanic or Latino	37.7% (n=658)
Not Hispanic or Latino	56% (n=979)
Unknown	6.3% (n=110)
Education (mean [SD], years)	13.6 ± 3.0
MMSE score (mean [SD], range)	24.9 ± 4.2 3–30

MCI, mild cognitive impairment; SD, standard deviation.
*Includes individuals with single race other than White, Black, or Asian, and those with mixed races.

Figure 1. Violin plots for age and MMSE.



Width of the shaded area represents kernel probability density; black dots represent individual data points; red dots represent group mean.

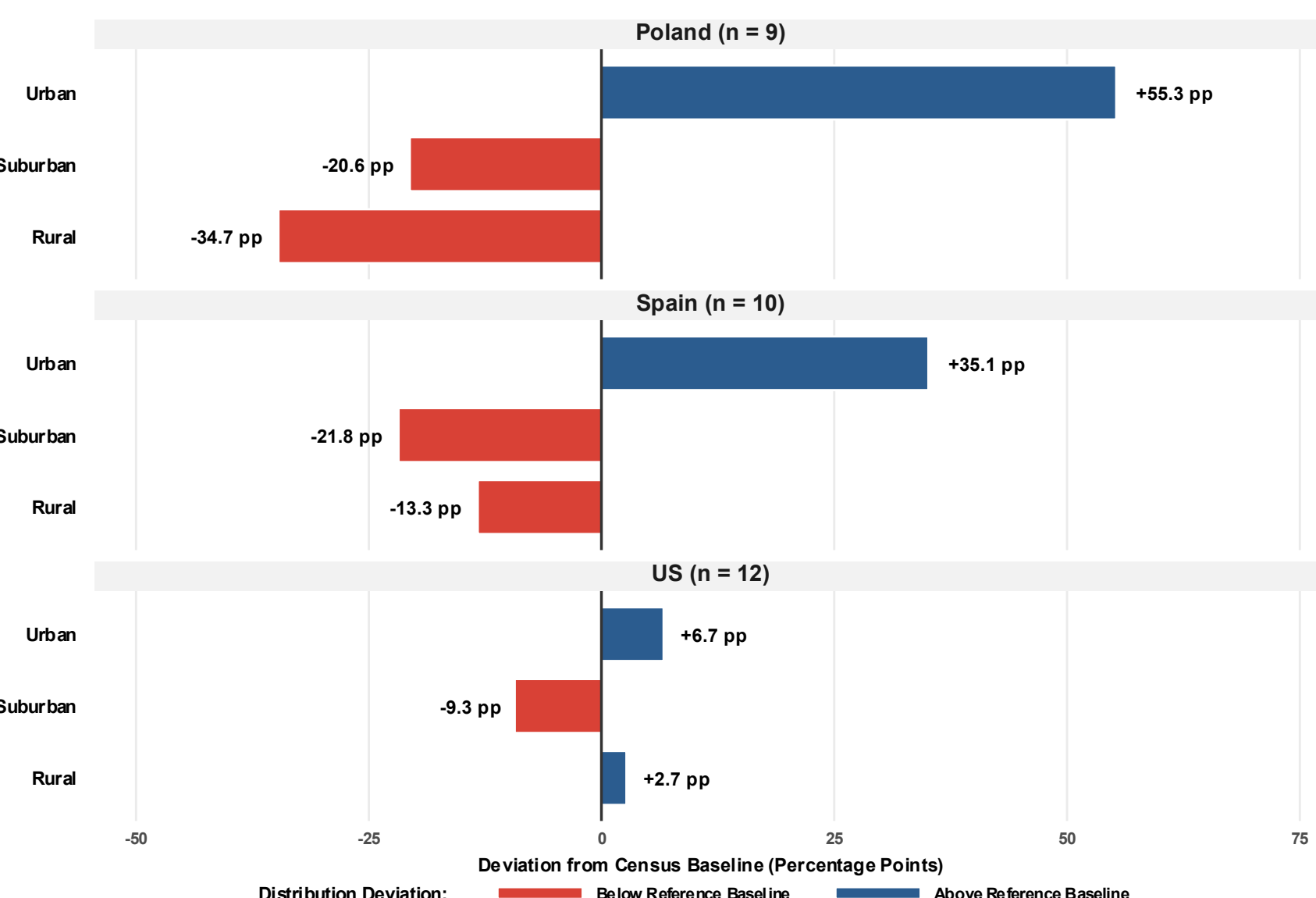
Conclusions

- **Operational efficiency:** A low-burden pre-screening protocol designed to identify potential candidates for interventional AD trials before they undergo invasive or high-cost clinical procedures
- **Geographic diversity disparity:** Enrolment diversity varied significantly by region. US cohorts achieved substantially broader socioeconomic representation than Spain and Poland
- **Community engagement:** Localised site selection coupled with outreach activities successfully captures wide variations in geographic, education and socioeconomic background

Results cont.

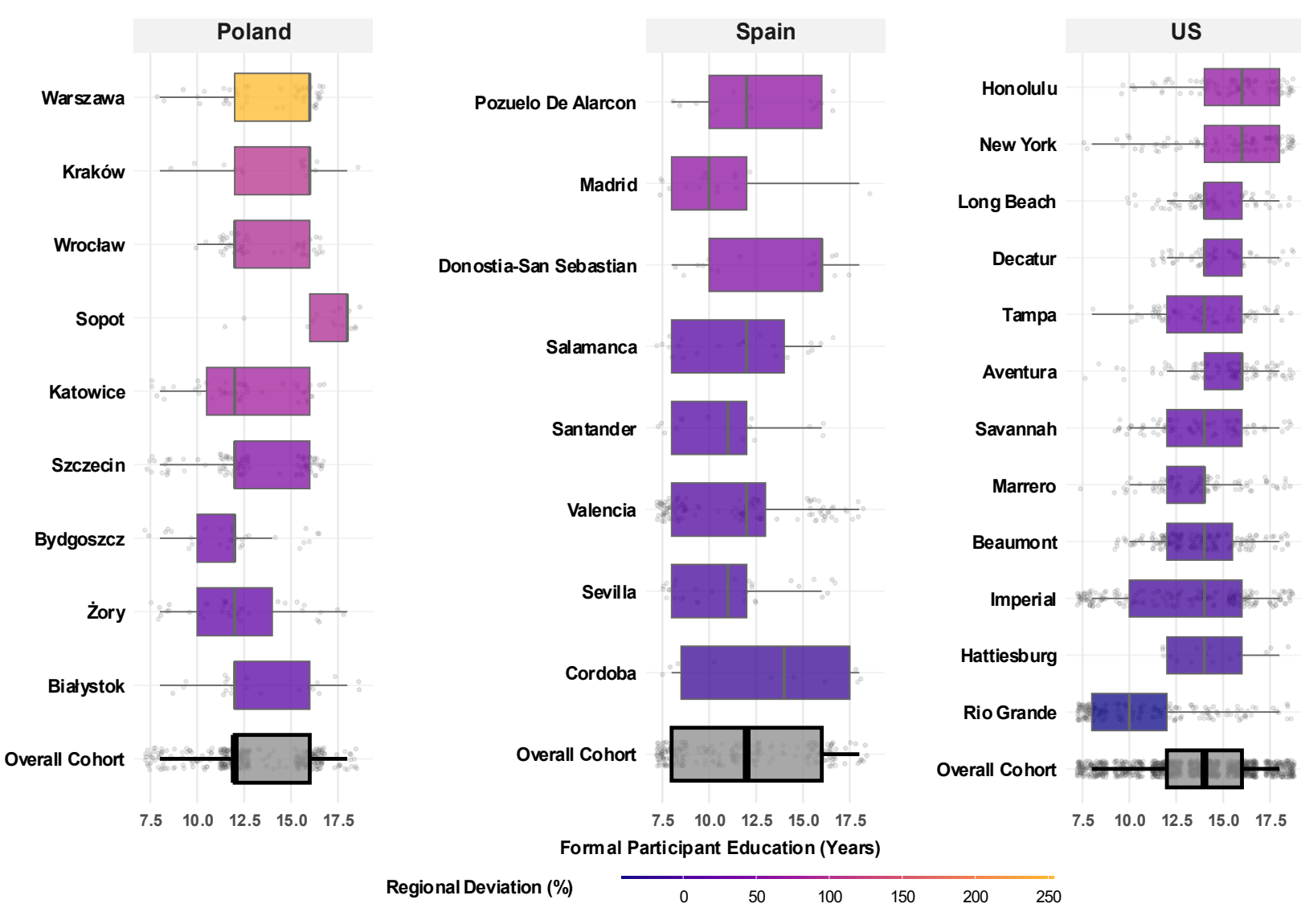
Site representativeness in geographic, socioeconomic and education context

Figure 2. Regional distribution of clinical trial sites compared with national baselines.



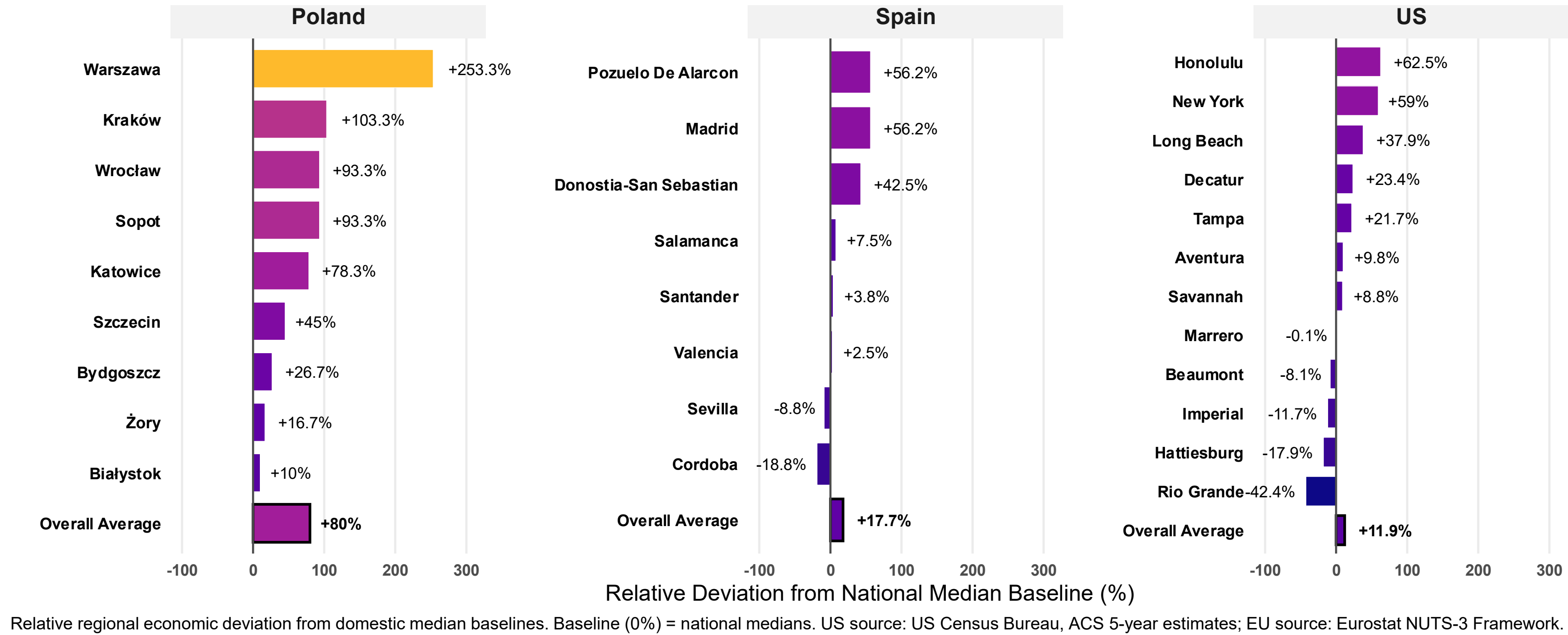
Percentage point deviations across urban, suburban and rural sectors in Poland, Spain and the US. Baseline (0) = parity with USDA Rural Urban Continuum Codes and DEGURA frameworks.

Figure 3. Participant educational attainment across sites ranked by regional SES.



Distributional covariance between local affluence and individual education levels. Sites ranked by descending regional SES deviation. Baseline (0%) = national medians. SES, socioeconomic status.

Figure 4. Socioeconomic characterisation of 31 clinical trial site catchment areas.



Relative regional economic deviation from domestic median baselines. Baseline (0%) = national medians. US source: US Census Bureau, ACS 5-year estimates; EU source: Eurostat NUTS-3 Framework.

Results summary

- Sites in the US compared to both Spain and Poland were more closely matching the national geographic distribution of rural vs suburban vs urban areas (Figure 2), and median household income (Figure 4)
- Education levels by site varied by country, with a stepwise pattern linking socioeconomic status to education years being more apparent in the US than Spain and Poland (Figure 3)
- Participants in Spain were somewhat older and had lower MMSE scores compared to those in US and Poland. Age and MMSE scores showed a relatively similar distribution across countries (Figure 1)

Disclosures

- **IK, EG, NM, KC, JT** and **RT** are employees of and shareholders in F. Hoffmann-La Roche Ltd
- **RC** and **CL** are employees of Roche Products Ltd and shareholders in F. Hoffmann-La Roche Ltd
- **LS** is a former employee of F. Hoffmann-La Roche Ltd

References

1. Langbaum JB, et al. Alz Dement 2022;7:696–707
2. Raman R, et al. JAMA Netw Open 2021;4:e2114364