

PP09: GSK Diversity Paper: The Challenges We Faced with Real-World Data

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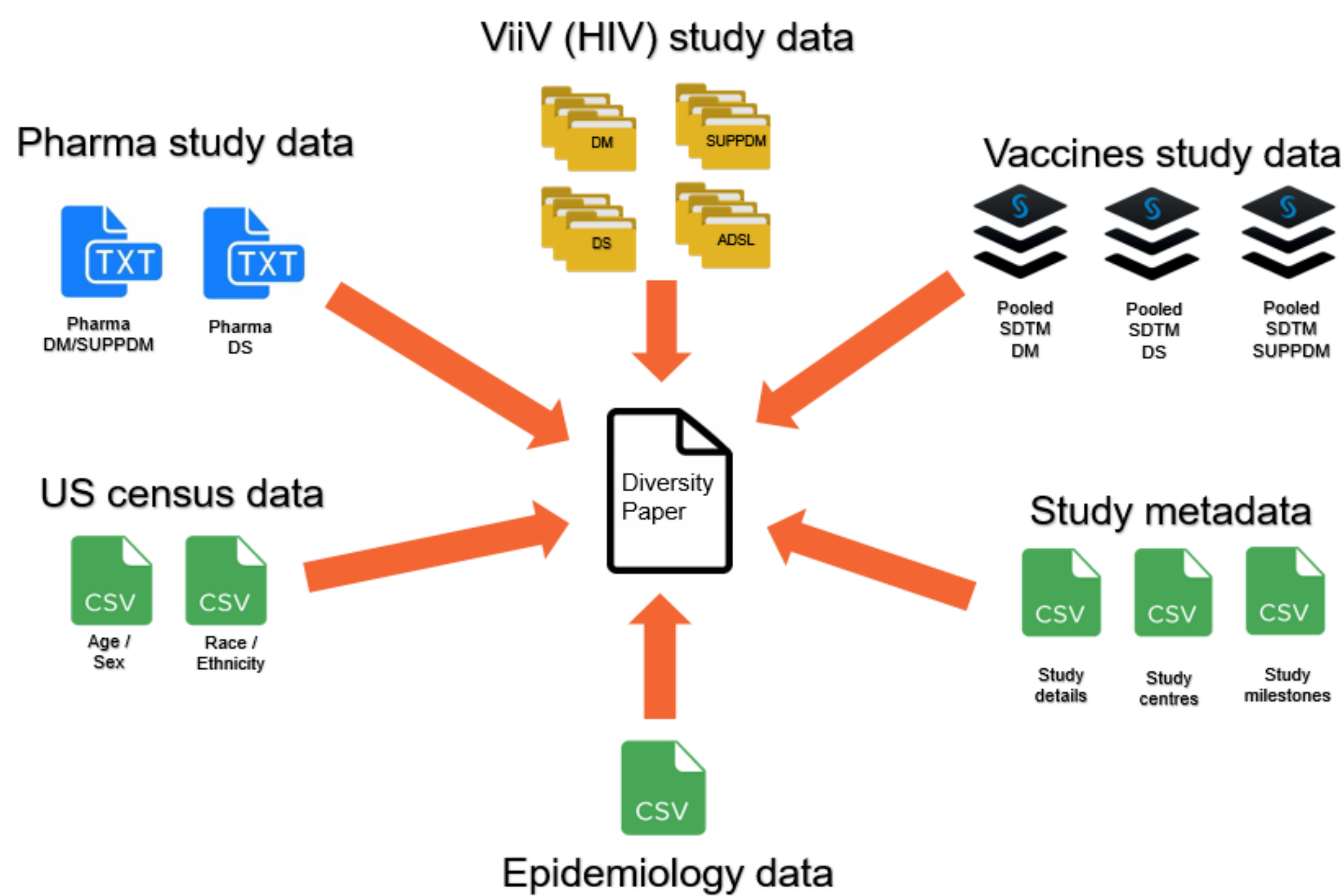
Introduction

- In early 2021, Pfizer published a paper titled ‘Demographic diversity of participants in Pfizer sponsored clinical trials in the United States’¹
 - The primary focus of their paper was to “provide a baseline upon which we can quantify the impact of our ongoing efforts to improve racial and ethnic diversity in clinical trials”
 - Analyzed data for 213 US trials between 2011 and 2020
 - Compared against US Census data²
- *Issued an industry wide challenge for other big pharma companies to release their diversity data

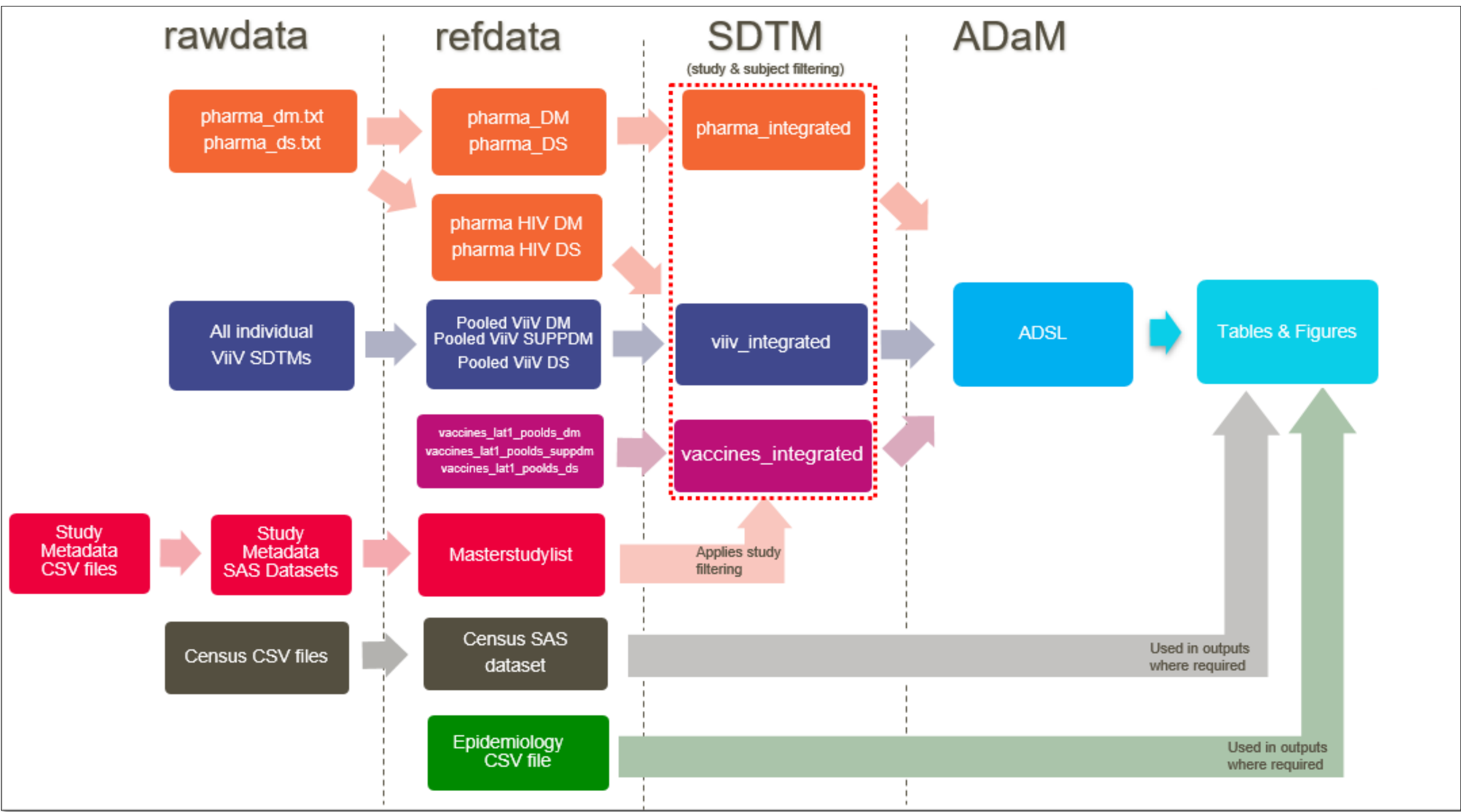
Objectives

- Summarize data for;
 - GSK sponsored interventional trials for Pharma, Vaccines & ViiV (HIV)
 - Studies conducted between 2002-2019
 - Trials that were completed and archived
- Reproduce all displays and supplemental displays
- Reproduce all census level comparisons
- Perform comparisons with real-world epidemiology data
- Summarize data for US Trials conducted between 2002-2019

Data Sources



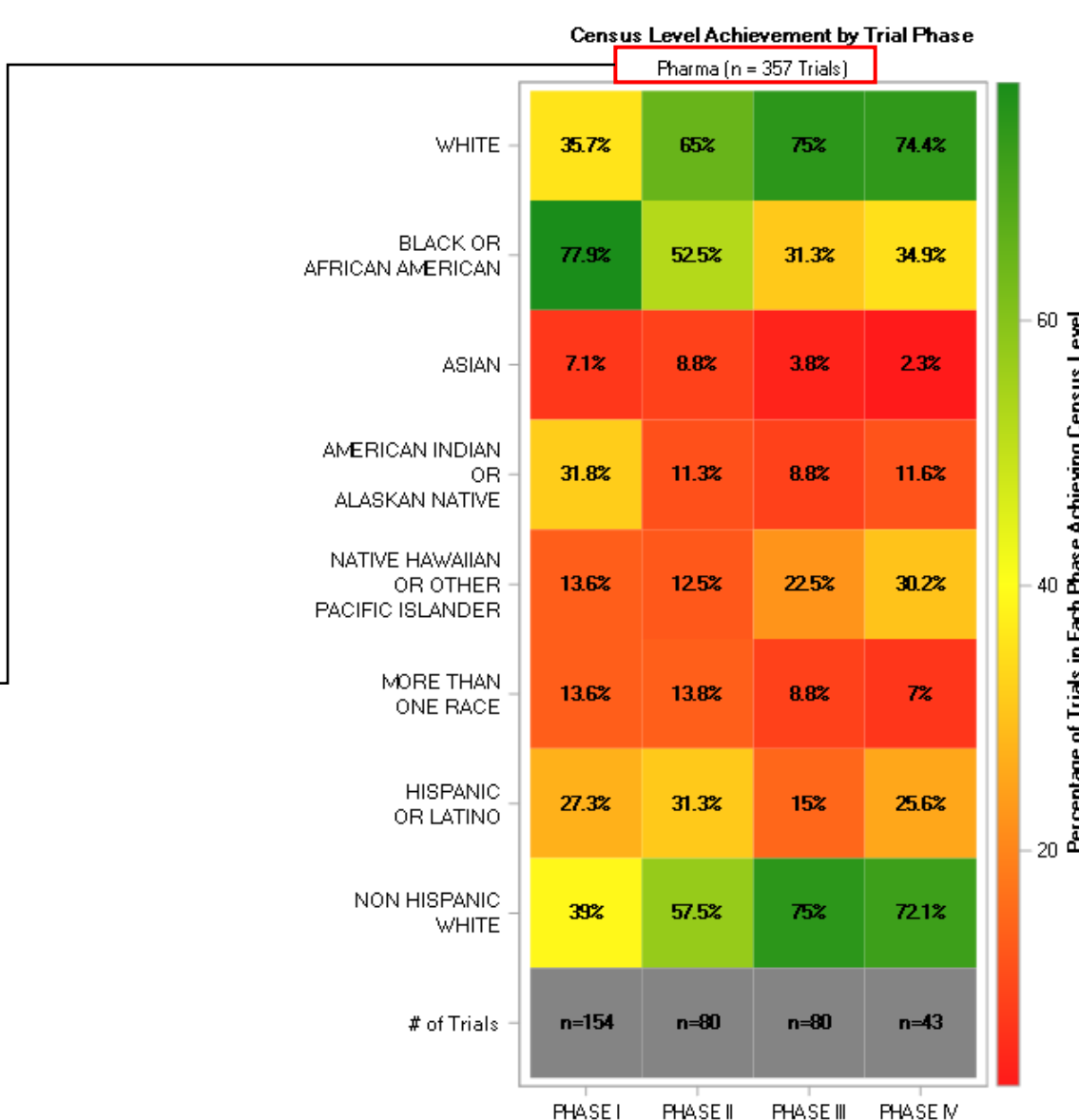
Methods



Results

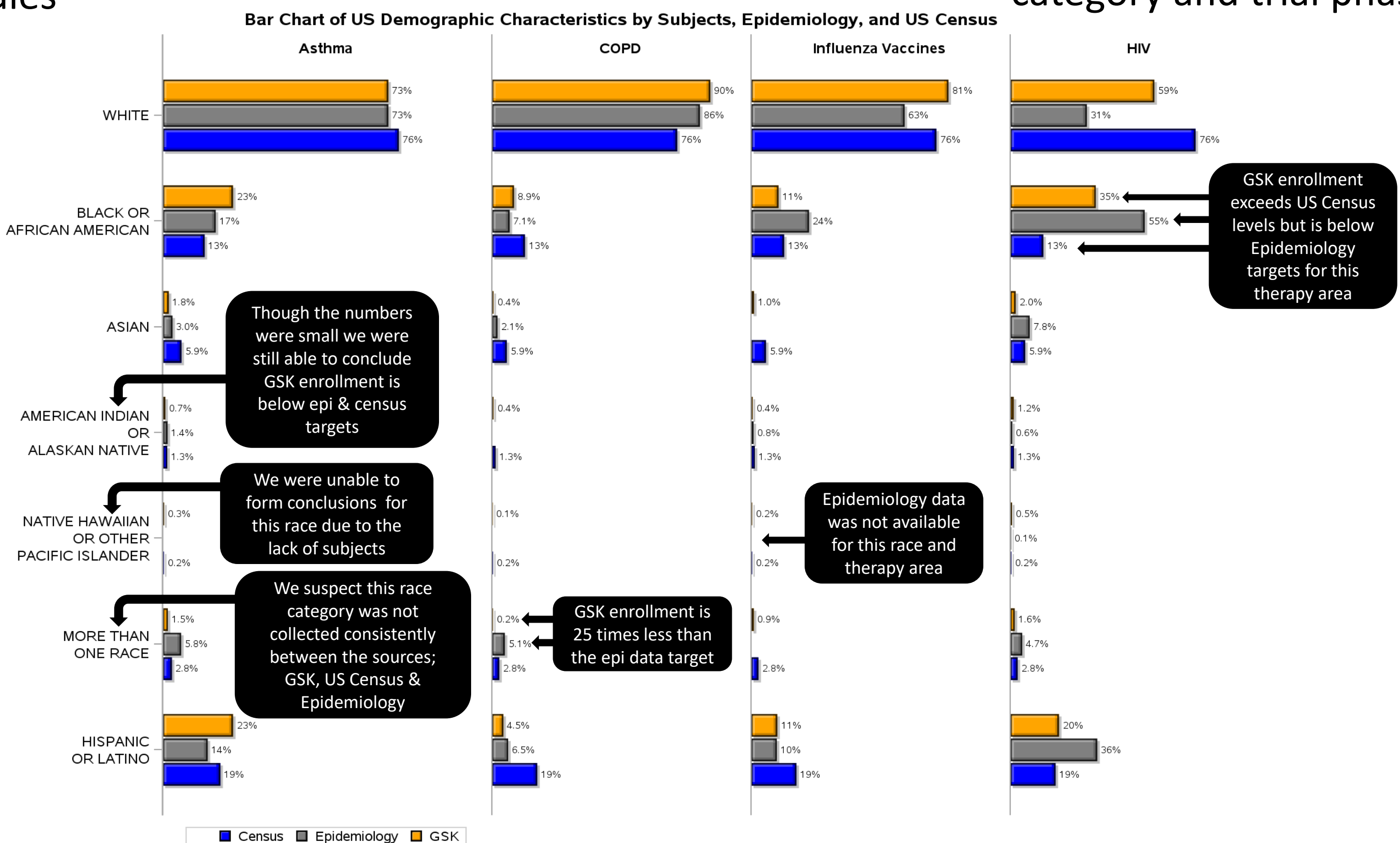
	Number of Subjects (1)	% of Subjects	Number of Clinical Trials (1)	% of Clinical Trials
Pharma Therapy Area	0	0.00%	0	0.00%
Autoimmune	9188	15.30%	52	14.57%
Cardiovascular Diseases	53	0.09%	4	1.12%
Gastrointestinal Diseases	245	0.41%	6	1.68%
Infectious Diseases (Non-HIV)	3161	5.26%	33	9.24%
Inflammation	534	0.89%	8	2.24%
Metabolic Diseases	4322	7.20%	43	12.04%
Musculoskeletal Diseases	567	0.94%	10	2.80%
Neurosciences	5687	9.47%	45	12.61%
Oncology	418	0.70%	14	3.92%
Ophthalmology	225	0.37%	2	0.56%
Other	28	0.05%	1	0.28%
Respiratory	34533	57.52%	121	33.89%
Urology	1077	1.79%	18	5.04%
Pharma Overall	60038	100.00%	357	100.00%
ViiV Therapy Area	5720	100.00%	93	100.00%
Infectious Diseases (HIV)				
Vaccines Therapy Area	42448	99.87%	40	88.89%
Vaccines Prophylactic	55	0.13%	5	11.11%
Vaccines Therapeutic	42503	100.00%	45	100.00%
Vaccines Overall				
Overall Therapy Area	108261	100.00%	495	100.00%

(1) The number of subjects and number of clinical trials are based on the total number of subjects and clinical trials within each therapeutic area category.



A table was produced summarizing the number of studies and subjects per TA category, for Pharma, Vaccines, and ViiV studies

A heatmap was produced showing the of % of studies achieving census level for each race/ethnicity category by TA category and trial phase



A horizontal bar chart of US Census, Epidemiology, and GSK clinical trials with race & ethnicity categories on the vertical x-axis and percent of the total population as the bar length

Challenges



Conclusions

By using real-world data, our team was able to unearth previously unanswered questions related to how GSK’s trial enrollment mirrored US Census and real-world epidemiology data³. GSK walked away with a pivotal understanding that US Census data is not an appropriate universal benchmark and that a shift to epidemiology data could serve a better purpose for improving diverse recruitment outcomes. Despite a team's best efforts to plan for everything beforehand, in our business we can always expect the unexpected. Despite the challenges, if a team begins with the end in mind, has a clear vision of the questions being asked, ensures all key stakeholders are involved in the planning stages, success is inevitable.

References

- Rottas, M. et al. (2021) Demographic diversity of participants in Pfizer sponsored clinical trials in the United States. Elsevier Inc.
- US by Sex, Race, and Hispanic Origin for the United States: April 1, 2010 to July 1, 2019 (NC-EST2019-SR11H), Release Date: June 2020. (Accessed 12 Jul 2021).
- Reid MM, Davis SP, Henry ON, et al. Demographic diversity of US-based participants in GSK-sponsored interventional clinical trials. Clinical Trials. 2023;0(0). doi:10.1177/17407745221149118

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