Leveraging a data-centric approach to improve representation in clinical studies

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BIO Clinical Trial Diversity Roundtable

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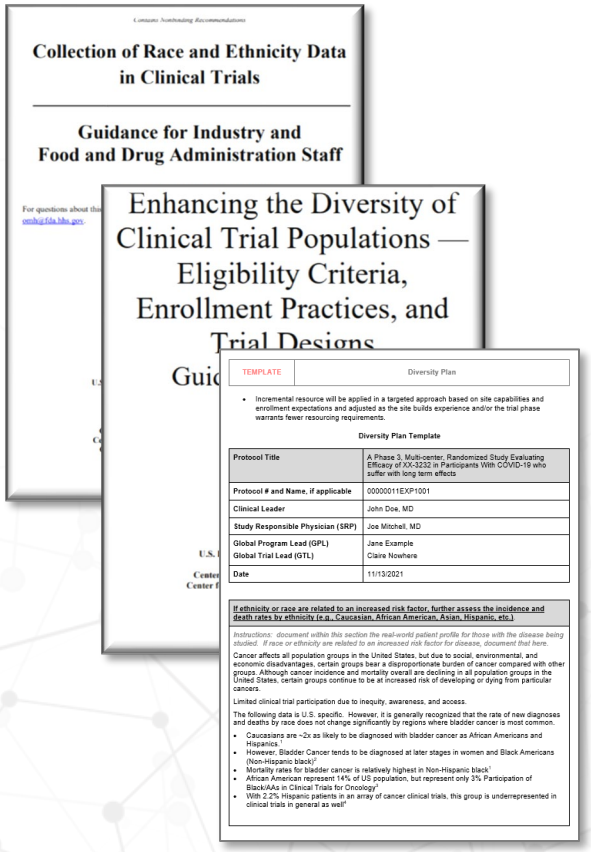
FDA & DIVERSITY: FDA provided recommendations to sponsors for developing a robust race and ethnicity diversity plan for all studies



FDA has previously released a guidance stating that **clinical trial populations must reflect the real-world population** - broad and representative regarding age, gender, race, and ethnicity. Recently the FDA Omnibus Reform Act of 2022 (FDORA) requires that sponsors submit a diversity plan with robust diversity recruitment tactics.

Recently, the FDA has updated their suggested recommendations for increasing diversity in clinical trials:

- **Broadening** eligibility criteria
- **Low burden** study designs
- **Diverse** recruitment & retention practices
- **Expanded** access
- **Increase** patient outreach and education
- **Partner** with underserved communities
- **Strategies** for the rare disease recruitment

Diversity plan should contain an overview of the disease, trial scope, DEI enrollment goals, plan for DEI recruitment & retention, and status of meeting enrollment goals.

Johnson & Johnson

OUR RACE TO HEALTH EQUITY

Our Race to Health Equity Credo is to help eradicate racial and social injustices as a public health threat by eliminating health inequities for people of color. To achieve this, JNJ strives to:

Reach 5 Million People of Color with more relevant, trusted, and culturally competent inclusive care, with emphasis on community-based solutions

Develop more relevant, trusted culturally competent health systems by **developing and supporting 200,000 health care professionals and researchers**

Achieve planned **diversity targets in 80% of clinical studies** that have a diversity and inclusion focus

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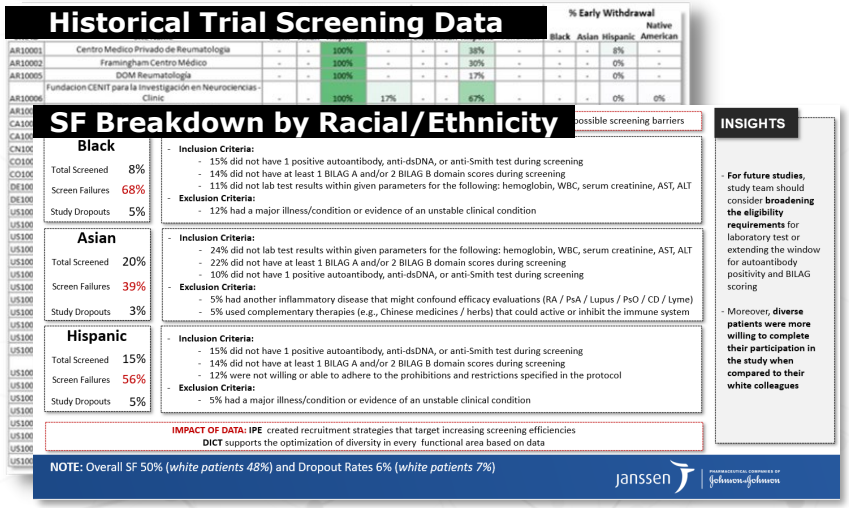
Inclusive protocols increases the chances of diverse representation during screening & randomizations

Many studies leverage previous trial protocols without fully assessing the impact of the exclusionary criteria, which leads to decreased eligibility for diverse patients. We utilize the following resources to help in this matter:

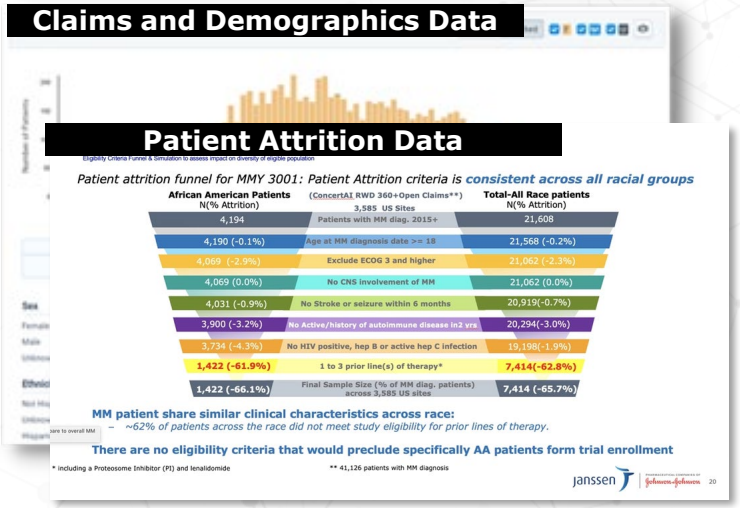
Screen Failure Analysis



Previous trial data allows us to uncover directional trends of screening criteria and highlight:

- Which I/E criteria are contributing to screen fails
- Reasonings for discontinued trial participation
- Opportunities for redefining criteria thresholds

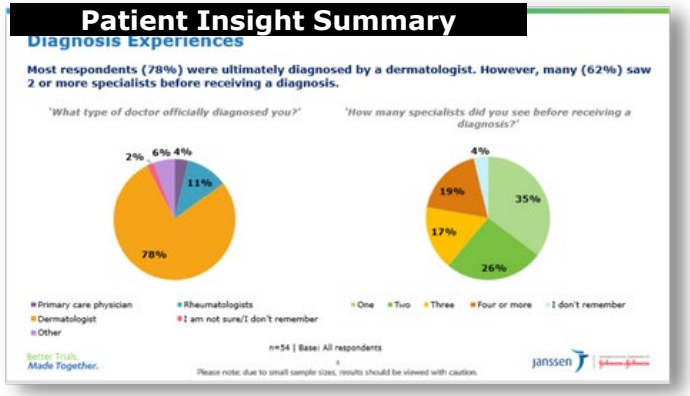
Patient Cohort Analysis



RWD curated by Data Science allows for disease specific patient analysis, when available, based on:

- Race, Ethnicity, Sex, and Age
- Medications and Procedures
- I/E Criteria and ICD-10 codes
- Lab Tests and Genetic Markers

Patient Voice Activities



By leveraging Patient Voice, we gather patient insights through panels and online surveys covering:

- Protocol design and challenges
- Unmet needs with current treatment and HCPs
- Awareness and perception of clinical trials
- Virtual trial elements – what works?
- Sensitivity input in logo and materials

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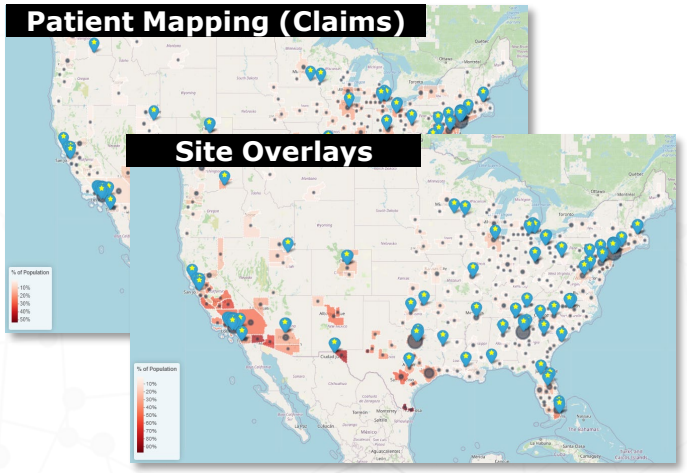
Leveraging data for site identification within diverse hot spots with robust diverse recruitment

Although large community hospitals and academic facilities have the experience, competition and lack of patient diversity can render these sites to be ineffective in our trials. To reflect a representative population, we help identify diverse sites and utilize the following resources:

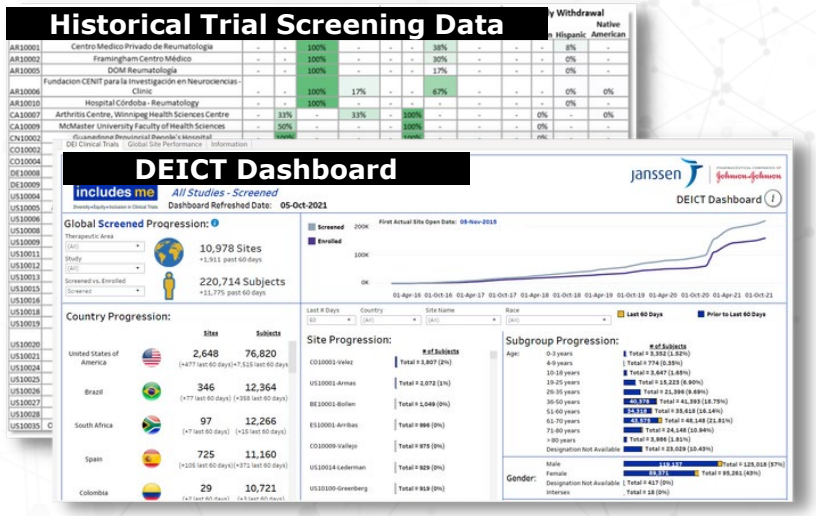
Patient Mapping (US only)



RWD patient claims mapping, aids in uncovering disease specific potential locales with:

- Areas to engage and recruit diverse patients
- Potential partnerships with naïve/experienced HCPs
- Areas where sites have low community engagement -

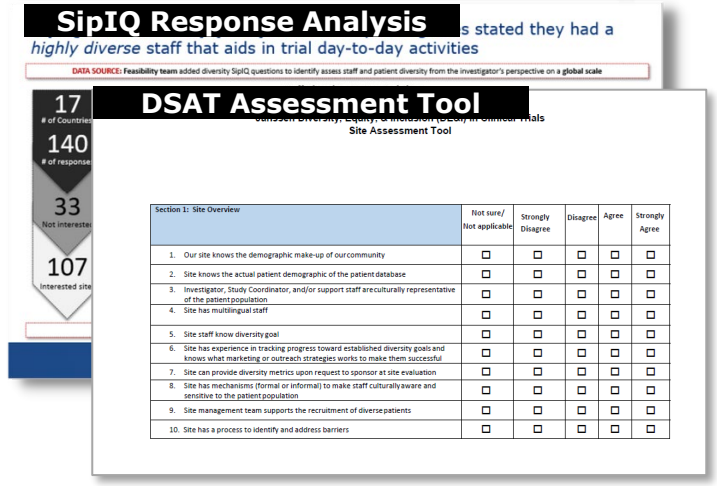
Enrollment Data (Global)



We have created a user-friendly diversity dashboard that showcases:

- Race & Ethnicity Distribution for Janssen trials
- Racial enrollment from 2016 to present
- Racial & ethnic distribution across multiple TAs
- Race enrollment at a site from Janssen trials

Site Voice (Global)



By adding diversity focused questions into the SipIQ and Diversity Site Assessment Tool we can:

- Validate race distribution data (US only)
- Identify sites with diverse staff
- Identify sites with resources for diverse patients
- Uncover sites practices for diversity engagement

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Case Studies & Impact of DEICT initiatives across various Disease Areas
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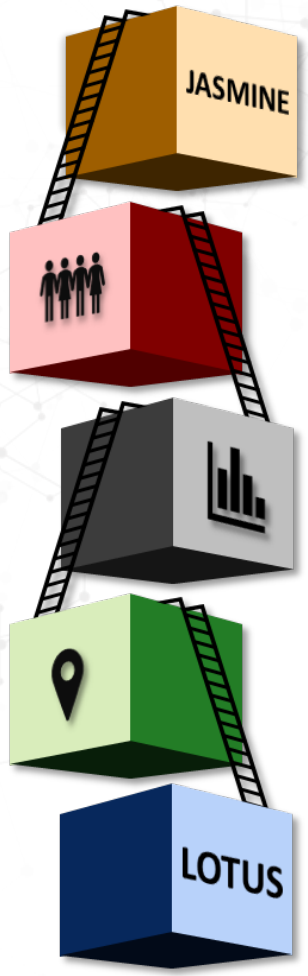
JASMINE: Building on lesson learned and leveraging DEI hot spots for robust recruitment

OVERVIEW

JASMINE is the phase IIa study within the system lupus erythematosus (SLE) disease area. It is evaluating the safety and efficacy of an investigational medication for those with moderate to severe SLE.

CHALLENGE

- **Enrollment occurring during COVID-19 pandemic**
- There is **high competition** within the trial landscape
- Low patient interest due **placebo arm**
- Patients unwilling to participate due to **exclusionary criteria**
- High prevalence among Black females but **extremely low participation** (<8%)
- Poor Black participation attribute to the **high screen failures** (**68%,** LOTUS)



Enhancing Community Engagement
Established partnerships with Patient Advocacy Groups and DEI vendors to increase trial awareness & tap into new patient pools

LUPUS RESEARCH ALLIANCE

DrugViu

Leveraging Patient Insights
Included sites with moderate to highly diverse staff based on site feasibility responses as well as included tactics that are responsive to patient insights

DS Partnership & RWD Utilization
Utilize RWD (e.g. claims & census data) to identify additional sites in diversity hot spots locations in the USA

For OUS, we leveraged historical recruitment data to identify OUS countries / sites that recruited diverse patients (Asian, Black, & Hispanic)

Leveraging Sites
Selected high performing LOTUS sites with strong sponsor relationships, bandwidth, and DEI opportunities

LOTUS Ph III
Served as the foundation for site selection / engagement, diversity goals, and recruitment success

SUCCESS THUS FAR

>60% Of selected countries have **historically recruited diverse patients**

~91% Of e**nrolled** participants **are female** (comparable to LOTUS of 90%)

JASMINE IS ON TRACK WITH DEI GOALS

9%	Asian Goal (8 – 11%)
7%	Black Goal (7 – 11%)
37%	Hispanic Goal (10 -14%)

~20 Number of **Black patients** vendors are slated to refer to JASMINE (~3 months)

VISIBLE: Filling in the gaps within dermatology with a first-of-its-kind skin of color (SoC) dedicated study

OVERVIEW

- Phase 3b study investigating the efficacy/safety of an investigational compound vs placebo in SoC patients with mod-sev PsO
- Aims to build a Skin of Color Image repository and gain novel scientific insights into issues like PIPA

CHALLENGE

- **Low utilization of dermatological services** amongst skin of color
- **Lack of clinical benchmarks & accurate presentation of dermatologic diseases on skin of color**
- **Darker skin tones** may present with less noticeable skin reddening**, making it difficult to truly assess active disease / inflammation**
- **Scalp psoriasis is very prevalent among non-white PsO patients,** yet representation remains low **(~10% of trial population)**

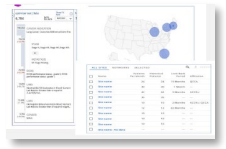
DEI Metrics

Recruit 200 self-identified non-white who are bio-naïve or experienced across all skin tones (I-VI)

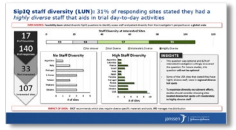
100% Skin of Color

DEI FOCUSED TACTICS

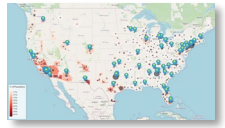
Leveraging Data



To **identify sites**, we **utilized our MSL network** and to identify potential diverse sites

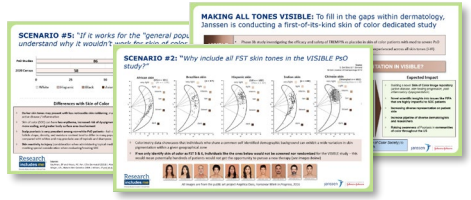


Conducted site feasibility with questions regarding **SoC experience** and communicated early on diverse enrollment requirements.



Targeted **geographic locations** across the United States based on diversity, target population.

Instilling Training & Tech



Created training decks for MSLs to empower prepare them for **challenging DEI conversations** with potential and selected Dermatology HCPs

Leveraging **colorimeter technology** to independently quantify skin tones – **aids in measuring pigmentation (melanin) and erythema**

Impactful Engagement

Leveraged **skin of color appropriate images and recruitment materials** to support HCPs, **drive referrals**, and **educate patients about the VISIBLE trial – we ensured that complex study details were written in layman terms for greater understanding**

Leveraged insights from diverse advisory boards of >30 leading SOC experts to refine our protocol and study elements that are equitable and more inclusive of the target demographic

Janssen has also partnering with leading medical and patient organizations (*e.g., AAD & Skin of Color Society*) to increase training and raise awareness of PsO as well as clinical research

CURRENT IMPACT

180 — **Patients screened:** 104 Body, 24 Scalp, and 52 Both

113 — **Patients randomized:** 35 FST I-III and 78 FST IV-VI

53% — **Randomized patients are Hispanic –** other top demographics are Asian (22%) and Black (13%)

IBD: Revamping engagement tactics and material design inspired by the patient's voice

OVERVIEW

Currently we have 4 IBD studies with overlapping country/site footprint and patient populations moderate to severe UC or CD. We are evaluating efficacy and safety of investigational compound(s).

CHALLENGE

- Recent studies highlight **prevalence is rapidly raising globally within non-white** communities (134% increased)
- **High internal and external competition** within the IBD landscape for both Bio-naïve and bio-IR patients
- **Recruitment of non-white Bio-IR patients will be challenging** due to low biologic usage among non-white IBD patients

DEI Metrics

GRAVITI	Non-white 20-35%
DUET-UC	Non-white 15-25%
DUET-CD	Non-white 15-25%
ASTRO	Non-white 15-25%

DEI FOCUSED TACTICS

Leveraging Data

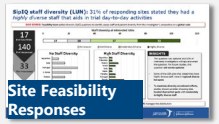
We have been able to **identify areas of DEI opportunity, better select sites, and identify screening challenges by demographics** by leveraging the following data:


Patient Cohort Analysis

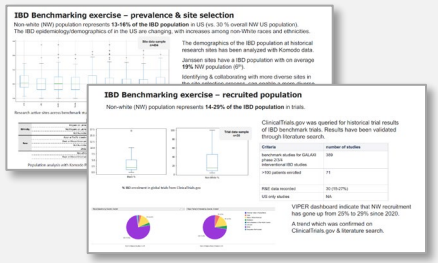

Diversity & Disparity Mapping (US)


Historical Recruitment Data


DEI Dashboard Analysis

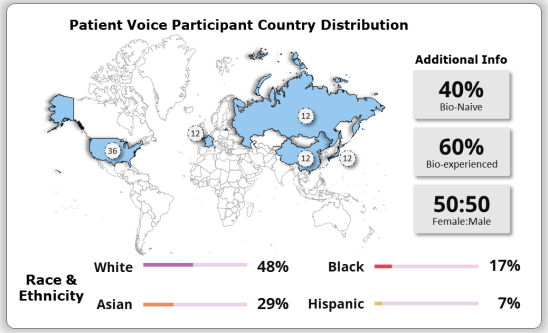

Site Feasibility Responses

Validated DEI metrics set for studies through **independent benchmarking analysis completed by DS**



Incorporating Patient Insights

To systematically improve clinical trials, we **incorporated patient insights** that are **representative of the real world** and identified challenges and motivations for **our IBD studies**:



Guinea Pigs
Some non-white patients view trial participation as serving as a *'guinea pig'*

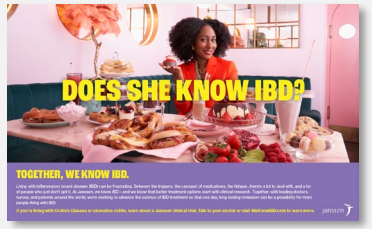
Distance Too Far
Some non-whites state clinical trials are not close to their home, which poses a barrier

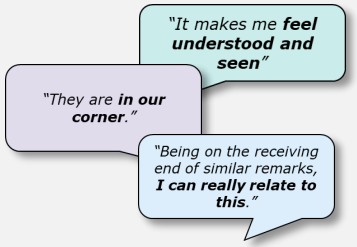
Low Awareness
Many hope that by participating in trials, they can increase awareness of IBD and drive trust

Not Enough Data
Some feel as the IBD community is suffering due to lack of research and representation

Impactful Engagement

Historically our site and patient facing materials have not been inclusive, therefore we revamped our materials to have better representation:





Strong Vendor Partnership

ACCLINATE™

Raise trial and disease awareness through digital (social media) and grassroot (clinics, churches, etc.) in Black communities

knowRX® HEALTH

Leverage Proximity Accelerator Tool to identify patient pools and decrease implicit bias through cultural considerations training

Q&A

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