



Patient Advocacy Groups:

Bridging Clinical Trials and Patient Communities for Meaningful DEI Impact

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Key Discussion Topics



Partnerships

- Understand the need for collaborative partnerships with patient advocacy groups



Insights

- Discuss valuable insights these groups provide into the patient journey, clinical trial design, and study participation to reduce barriers faced by diverse patient populations



Best Practices

- Share best practices for leveraging advocacy groups to enhance patient recruitment and retention



Premier Progress

- Explore how patient advocacy groups help align the objectives of clinical trials with broader diversity and inclusion goals

Recent Administration Changes on DEI in Clinical Trials

What's changed?

FDA removed previously issued draft guidance on diversity in clinical trials from its website in response to executive orders by the new administration



Impact of New Administration Changes on DEI in Clinical Trials



Intent behind the guidance

The draft guidance aimed to expand the inclusion of under-represented populations in clinical trials to improve the data we have for the intended use population of the product if approved



Implications

Focus on inclusion of appropriate populations to ensure scientific rigor; historical under-representation in clinical trials, such as cardiovascular research, highlights the importance of diversity and inclusion for generalizable and effective medical findings



Scientific Rationale to Support Diversity & Inclusion in Medical Research

Inclusion of Women in Clinical Trials: A Historical Overview of Scientific, Ethical, and Legal Issues

- In the past ~50 years, both **scientific and ethical perspectives** regarding **inclusion of women in clinical trials** of new biomedical products **shifted dramatically**¹
- Inclusion of **women of childbearing potential in early phase studies** shown to have **important scientific relevance** to understanding pharmacokinetic (absorption, bioavailability, distribution, metabolism, and excretion) differences by gender¹
- For example, certain cardiovascular drugs are **metabolized more slowly in women**, therapeutic agents such as acetaminophen and aspirin have **lower rates of clearance in women**, and **hormonal variations** associated with the menstrual cycle, menopause, or oral contraceptive use may result in **differing drug effects**¹



1. Merkatz RB. 1997. Inclusion of Women in Clinical Trials: A Historical Overview of Scientific, Ethical, and Legal Issues. JOGNN 27:78-84;

Scientific Rationale to Support Diversity & Inclusion in Medical Research



Cancer Care and Clinical Trials: A Need to Improve Equity for Underserved Racial and Ethnic Groups

- Black Americans comprise at least 13% of the general population in the US; however, **Black Americans remain under-represented** in cancer **clinical trials**²
- Taking MM as an example, a cancer in which **Black Americans account for about 22% of yearly cases**, the **median enrollment** percentage of **Black Americans in clinical trials** submitted in support of MM indications was **4.5%**²
- Similarly, **breast cancer and cardiovascular-specific mortality** are **higher among blacks** compared with whites, but disparities in **cancer therapy-related adverse cardiovascular outcomes have not been well studied**³



Patient Advocacy Group Partnerships



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Best Practices

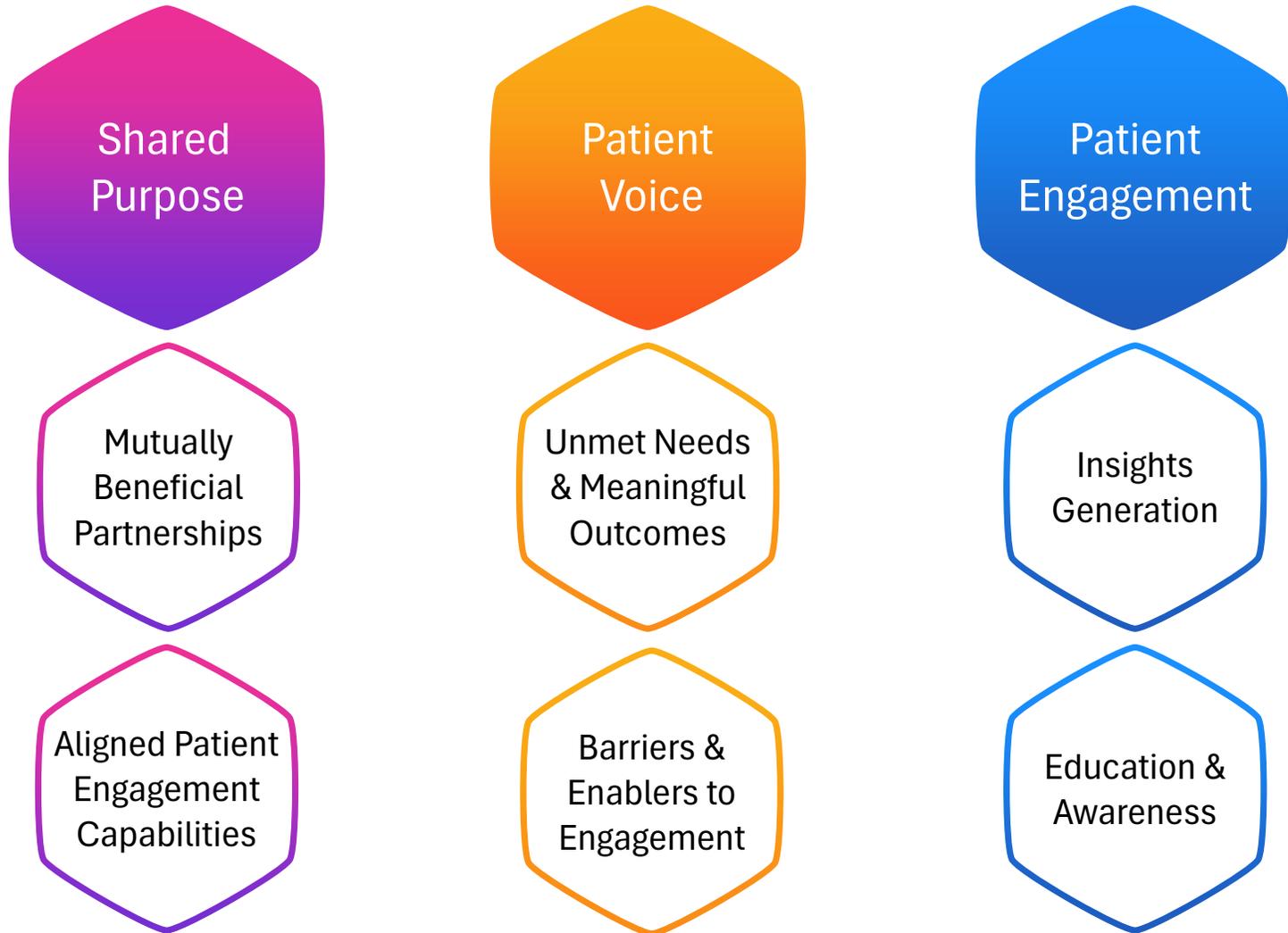
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Keys to Successful PAG Partnerships



It's **important to find the right match** for the **right patient engagement** activity in medical research⁴

Insights Generation



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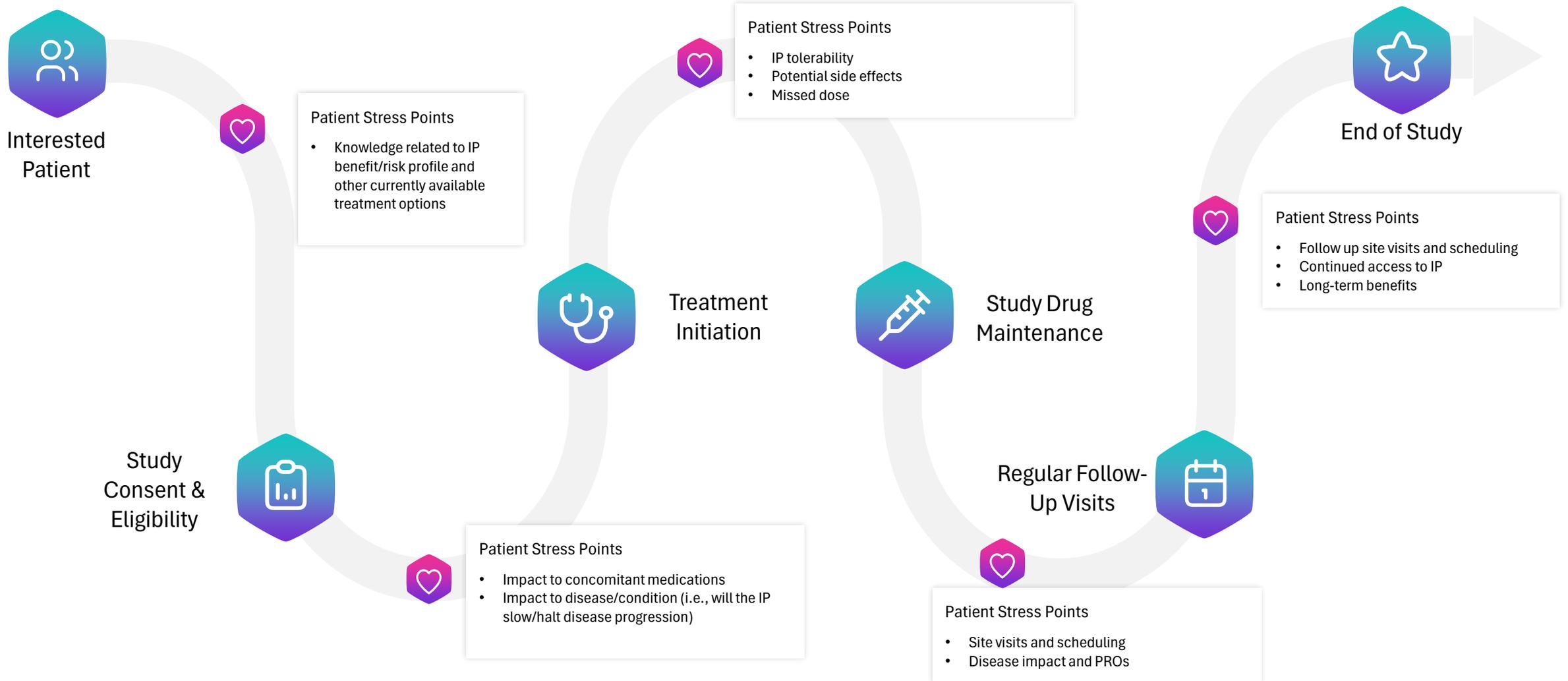


Premier Progress

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Putting the Patient Front and Center in Clinical Trials

Informing Potential Challenges and Areas for Improvement in Your Clinical Trial Design



Patient Insights for Clinically and Commercially Aligned Assets



Direct patient engagement to inform asset development and educational needs

Leveraging patient advisory boards, patient focus groups, and social networks to gather insights, define and close gaps, and support educational needs



Clinical trial design input to ensure meaningful outcomes supporting asset adoption

Ensuring patient input into study design and feasibility⁵



Stakeholder feedback to inform on barriers and enablers to study participation

Patient-centric approach informing study logistics and technology advancements⁵

Best Practices for Patient Recruitment and Retention



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Patient Advocacy Engagement to Support Study Success

Proactive Approach

Forging **strong patient advocacy relationships** to:

- **Elevate** the patient voice
- **Enhance** overall study experience for both patients and sites
- **Augment** patient recruitment and retention
- **Support** diversity and inclusion in medical research



Foster and/or develop foundational **relationships with key PAGs**



Align PAG capabilities and engagement based upon **mutually beneficial partnership opportunities** and likelihood for success



Finalize pathways to identify, engage, and raise **patient awareness** and **support trial enrollment**



Deliver aligned tactics with PAG partners, including detailed scope of work and KPIs to inform on patient recruitment and retention



Implement advocacy review process of study-specific tools and tactics across stakeholders

PAG Engagement Supports D&I Goals



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Grounded in Science

- From a scientific perspective, it's important that clinical research is reflective of appropriate patient populations
- Inclusivity ensures representation within medical research enabling generalizability of research findings across appropriate patient populations and broader understanding of the disease or medical product under investigation
- Representative clinical studies are needed to achieve more equitable study programs, not just large Phase 3 pivotal trials
- Under-representation in medical research has significant implications on patient outcomes and can negatively impact patient confidence in new treatment options



Supported by Partnerships

- PAG partnerships are critical to elevate the patient voice, insight generation, and patient engagement
- Other important factors to ensure drug/device development appropriately reflects patient populations include:
 - Partnering with researchers and study sites that better represent the communities they serve
 - Engaging with communities and historically underserved regions to:
 - Improve trust
 - Provide education
 - Support access to clinical studies and participation

Industry Partnerships Supporting Clinical Trial Inclusion Goals

Reflections: Independent, grassroots collective of patient advocacy experts, medicine development sponsors, advocacy groups, clinical trial sites, community partners, and communication specialists aiming to sustainably improve diversity in and access to clinical research participation

Mission: Drive awareness, education, and access to clinical trials with a focus on expanding diversity and inclusion in medical research



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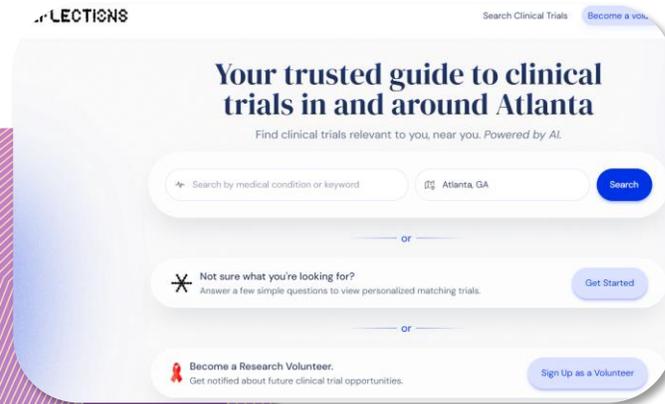


Reflections Cross-Industry Partnership



Reflections Consortia

Premier Research Participation in Cross-Industry Consortium to Drive D&I and Access to Clinical Trials



Clinical research should reflect us all.

Reflections is a groundbreaking program that uses art to highlight the importance of diversity in medical research. Your involvement in clinical trials makes a difference.

Are you reflected?



Join us at
[BeReflected.org](https://www.bereflected.org)



Tag your experience
@reflections.collective

Visit us at:
Ponce City Market
675 Ponce De Leon Ave NE, Atlanta, GA 30308

February 5 - March 30
Daily from 4pm to 9pm

