Click a resource to learn how organizations are using it to advance diversity, equity, and inclusion in digitized clinical trials.
Implement Digitized Clinical Trials

**Althea.ai**

**Amgen**

**Inlightened**

**Lightship**

**Medable**

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**Implementing Digitized Clinical Trials**

**Digital Recruitment & Retention**
Digital tools to streamline all steps in the trial process that require engagement of participants and clinical staff.

**Digital Health Data Collection**
Digital tools to enhance and expand data collection and integration with additional sources.

**Digital Analytics**
Digital tools to integrate, analyze, and report data and findings from clinical trials.

**Digital Readiness**
Strategic planning upstream to designing and throughout the clinical trial cycle.
Partnering with organizations across the continuum of care, Althea.ai delivers predictive analytics through its proprietary AI and ML solutions to help organizations strategically manage patient risk and provide clinically integrated care to improve health equity.

Althea.ai’s full-service platform includes curated and comprehensive datasets of Social Factors impacting individual health.

Althea’s insights focus on early disease detection, identification, and risk stratification, paired with care management systems to drive member engagement and behavior change to affect outcomes.

The Opportunity

The Resources

The steps of a Digitized Clinical Trial are detailed in the Implement Digitized Clinical Trials resource.

1. Start with assessing digital readiness to develop a strategic plan to implement digital tools to focus on diversity, equity, and inclusion.
2. Learn which tools can be applied to each step of the clinical trial process to optimize efficiencies and improve overall success.

The Impact

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource allows for better planning for all stages of the clinical trial.

Althea’s curated datasets can be used during digital readiness, recruitment and retention, and health data collection to drive goals for diverse, equitable, and inclusive Digital Clinical Trials.

Althea transforms data into actionable insights to enable diverse, equitable, and inclusive digital clinical trials.

— Ashish Chaturvedi, CEO, Althea.ai
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives.

Ensuring that we are bridging any digital divides in terms of access, user experience, and relevance and that we are using technology thoughtfully and inclusively, and have the potential to drastically improve the recruitment and retention of diverse and representative participant populations; that’s something we are really excited about.

— Racquel Racadio, Director, Representation in Clinical Research, Amgen

The Opportunity

Part of bringing research to where potential participants live, work, pray, and play includes using resources that take advantage of digital tools for education, awareness, and even participating in research itself.

Bridging any digital divides and ensuring that the use of technology is thoughtful and inclusive is critical to these efforts.

The Resources

The steps of a Digitized Clinical Trial is detailed in the Implement Digitized Clinical Trials resource.

1. Start with assessing digital readiness to develop a strategic plan to implement digital tools to focus on diversity, equity, and inclusion.
2. Learn which tools can be applied to each step of the clinical trial process to optimize efficiencies and improve overall success.

The Impact

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource allows for strategic planning and specific applications of all digital tools.

Amgen is bridging the digital divide and ensuring that technology use is intentional and inclusive with the potential to drastically improve the recruitment and retention of diverse and representative participant populations.
Lack of diverse representation in clinical trials also applies to clinical trial personnel; and like most solutions that start at the top, it begins with investigators.

Inlightened has demonstrated the power and potential of digital to diversify the clinical trials workforce — particularly with the expansion of the pool of minority principal investigators — helping to build trust, improve the diversity of clinical trial participants, and better demonstrate the safety and efficacy of new medicines in all populations.

The Opportunity

The Resources

The steps of a Digitized Clinical Trial is detailed in the Implement Digitized Clinical Trials resource.

1. Start with assessing your digital readiness to develop a strategic plan to implement digital tools to focus on diversity, equity, and inclusion.
2. Learn which tools can be applied to each step of the clinical trial process to optimize efficiencies and improve overall success.

The Impact

Inlightened was founded on the principle that diverse insights are key to advancing healthcare innovation for all. Ensuring clinical trial personnel are empowered with information and tools to optimize their experience will support their ongoing involvement, and that of the patients who have historically been so underserved.

— Shelli Pavone CEO & Co-Founder, Inlightened
Lightship’s people-first approach to clinical trial design and execution makes it easier for patients and caregivers to become an active part of clinical research. By offering more options for participation and harnessing the most cutting-edge technologies in patient engagement and data analysis, Lightship creates inclusive clinical trials that deliver more life-saving therapies to those in need.

Decentralized clinical trials and the use of digital technologies can be complex, which means careful planning is required to support diversity.

— Sepehr Shojaei Vice President, Design Solutions, Lightship
**Medable**’s mission is to bring trials to everybody, everywhere and get effective therapies to patients faster. Medable provides an end-to-end, global cloud platform with a flexible suite of tools that allows sponsors, patients, providers, & CROs to work together as a team in clinical trials. Medable’s solutions enable more efficient clinical research, more effective healthcare delivery, and more accurate precision and predictive medicine.

**Participating in the DiMe project on Diversity, Equity and Inclusion provided a suite of methodologies and techniques to explore. The resources being shared are adaptable, implementable inputs which are informing Medable’s Diversity Equity and Inclusion strategy.**

— Pamela Tenaerts, MD, MBA, Chief Scientific Officer, Medable, Inc.

**The Opportunity**

- Medable is actively using all the resources developed during the Diversity, Equity, and Inclusion in Digitized Clinical Trials project, as one of the active inputs to develop a diversity strategy.
- Diversity, equity and inclusion are central to Medable’s work and are the driving force behind the use of digital tools for Decentralized Clinical Trials.

**The Resources**

- The resources contained in the Specific Actions to Enroll & Retain Diverse Participants workbook is designed to guide those designing and implementing clinical trials with developing a Diversity Plan to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials.
- The Specific Actions workbook includes resources to help the clinical trial industry use digital tools throughout the clinical trial life cycle, by focusing on advancing diversity, equity, and inclusion.

**The Impact**

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resources are action-oriented and can be implemented immediately to address many of challenges facing the clinical trials.
- These resources can also guide the implementation of Decentralized Clinical Trials workflows.
Medable’s mission is to get effective therapies to patients faster. Medable provides an end-to-end global cloud platform with a flexible suite of tools that allows sponsors, patients, providers, & CROs to work together as a team in clinical trials. Medable’s solutions enable more efficient clinical research, more effective healthcare delivery, and more accurate precision and predictive medicine.

Digital tools are transforming medical research and bringing powerful benefits to study teams and participants.

Decentralized clinical trials use digital tools that are user-friendly, like smartphones, tablets and wearables, to enable patients to participate in clinical trials from the comfort of their own homes, rather than traveling to study sites.

These innovations bring advantages like faster and more focused enrollment, longitudinal data to better understand the participant experience, better participant diversity, stronger engagement and retention, improved clinical safety, cleaner and more accurate data and tremendous cost savings.

— Ingrid Oakley-Girvan, Senior VP of Strategy and Value, Medable, Inc.

The steps of a Digitized Clinical Trial is detailed in the Implement Digitized Clinical Trials resource.

1. Start with assessing your organization's' digital readiness with developing a strategic plan to implement digital tools to focus on diversity, equity, and inclusion.

2. Learn which tools can be applied to each step of the clinical trial process to optimize efficiencies and improve overall success.

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource will help alleviate pain points in implementing DCT components into studies.

These technologies can be adapted to best serve the patient population, condition, or therapy you’re investigating.
At Althea.ai digital tools are accelerating actionable insights and interventions to drive clinical outcomes and health equity. — Ashish Chaturvedi, CEO, Althea.ai

**The Opportunity**

- Real-World Data/Real-World Evidence (RWD/RWE) can be a powerful tool for each step of the clinical trials process.
- Althea uses RWD/RWE and Artificial Intelligence/Machine Learning (AI/ML) to deliver highly actionable and trusted predictive analytics through its proprietary AI and ML platform to help organizations strategically manage patient risk and provide clinically integrated care to improve health equity.

**The Resources**

- The Elements of a Digitized Clinical Trial resource demonstrates how digital tools can transform the clinical trials industry.
  1. Learn how each tool can be applied to each step of the clinical trial process to optimize efficiencies and improve overall success.
  2. See the digital tools in action, right now, with evidenced based resources and references.

**The Impact**

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource provides details on value of digital tools such as RWD/RWE, AI/ML, and Digital Platforms for clinical trials.
- RWD/RWE allow for deeper insights that can be valuable with accessing more and diverse participants, and designing inclusive trials.
Inlightened's digital solution offers a SaaS-based network of vetted healthcare experts representing diverse communities and therapeutic areas.

The Inlightened platform facilitates onboarding, contracting, scheduling, and payment, easing the administrative burden of interacting with industry. The digital network established by Inlightened allows for a unique understanding of specialized expertise, the communities that investigators serve, and their depth and breadth of clinical research.

The Elements of a Digitized Clinical Trial resource demonstrated the potential of digital tools to transform the clinical trials industry.

1. Learn how each tool can be applied to each step of the clinical trial process to optimize efficiencies and improve overall success.
2. See the digital tools in action, right now, with evidenced based resources and references.

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource highlights the value of digital platform and solutions.

Our network of providers are engaged and aligned in their commitment to use their diverse insights to advance healthcare innovation for all.

— Shelli Pavone  CEO & Co-Founder, Inlightened

By providing opportunities for more diverse clinicians to participate, Inlightened builds trust with our community of providers so that they feel comfortable sharing their expertise and knowledge with client partners from across the clinical trials ecosystem.

Inlightened is passionate about optimizing healthcare innovation for all. The Inlightened platform democratizes access to the only marketplace of curated, vetted, and engaged clinicians and healthcare professionals, passionate about shaping the future of their fields. This technology effectively eliminates the administrative burden — with unprecedented transparency, and automated vetting, contracting, scheduling, and payment — so our members can focus on the task at hand: Disrupting responsibly.
Lightship’s people-first approach to clinical trial design and execution makes it easier for patients and caregivers to become an active part of clinical research. By offering more options for participation and harnessing the most cutting-edge technologies in patient engagement and data analysis, Lightship creates inclusive clinical trials that deliver more life-saving therapies to those in need.

During protocol evaluation, Lightship can identify opportunities for digitization and incorporate those tools into proposed delivery models. For those studies focused exclusively on equity, Lightship offers point-by-point guidance on leveraging Lightship’s digital toolkit.

From initial design to study closeout, Lightship offers more choice and more flexibility to achieve greater patient access. In doing so, Lightship accelerates the development of better therapy options for everyone.

The Elements of a Digitized Clinical Trial resource demonstrated the potential of digital tools to transform the clinical trials industry.

1. Learn how each tool can be applied to each step of the clinical trial process to optimize efficiencies and improve overall success.

2. See the digital tools in action, right now, with evidenced based resources and references.

The Opportunity

The Resources

The Impact

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource will help increase access to clinical trials by increasing efficiencies for participant engagement, enrollment, and retention.

The Lightship team provided insights into accelerating timelines and improving workflow efficiencies with decentralized modalities.

Work by the Diversity, Equity, and Inclusion in Digitized Clinical Trials project team helped us identify the various ways digital tools can create more access for clinical trials.

— Sepehr Shojaei Vice President, Design Solutions, Lightship
Reveles Clinical Services is a purposeful Decentralized Clinical Trial Management company that aims to eliminate zip code from being a barrier to participating in clinical trials for all patients. For biopharma, diagnostics, digital health, and CROs, Reveles closes the access gap and accelerates the clinical trial process by enabling patients to participate from the comfort of their homes.

DCT brings a unique set of challenges and significant concerns around “trust”. As clinical data and documents are being collected by, store in, and exchanged an increasing number and variety of systems and devices, trial stakeholders struggle to ensure integrity and authenticity of the research data. As result, we believe that blockchain and distributed ledger technology can improve accuracy, encourage data sharing, and ensure regulatory compliances. — R’Kes Starling, CEO, Reveles Clinical Services

The Opportunity

- Reveles leverages a robust blockchain-based software platform and a curated, certified, and trained network of local healthcare providers to optimize the patient’s and principal investigator’s end-to-end experiences.
- The Reveles platform manages the patient experience throughout the trial, connects patients with site personnel, and facilitates telehealth and remote data collection from variable sources such as wearables, devices, and PROs.

The Resources

- The Elements of a Diverse, Equitable and Inclusive Digital Clinical Trial resource demonstrate how digital tools can transform the clinical trials industry.
  1. Learn how a variety of digital tools are being used to increase efficiencies at each step of the clinical trial process.
  2. See the digital tools in action, right now, with evidenced based resources and references.

The Impact

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource highlights the power and variety of digital platforms and solutions to address clinical trials challenges.
  1. Reveles is accelerating the clinical development process by leveraging advanced technology solutions that improves patient recruitment and retention to make research accessible to all.

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R’Kes Starling, CEO, Reveles Clinical Services
Rubix Life Sciences (Rubix LS) is wholly focused on changing the nature of life-science research that encompasses precision medical science devoted to inclusive clinical research. Founded in 2016 by Reginald Swift Ph.D, Rubix LS is a digital life research and development company focusing on creating processes and innovations that are focused on patient health and greater patient health outcomes.

Customized solutions are needed to advance public health and to make a difference and create products for people who could not see the light of day or gain that access. Rubix’s digital platforms will allow us to launch solutions tailored at every stage of development.

— Reginald Swift, Founder and CEO, Rubix, LS

The Opportunity

- **StarSense** is Rubix LS’s digital platform/solution for creating more inclusive clinical trials.
- As life science and healthcare companies look to drive inclusivity into clinical trials, Rubix LS is enhancing these approaches with the help of the digital platform, StarSense, to ensure comprehensive and robust advancements are realized to reach all patients.

The Resources

- The [Elements of a Diverse, Equitable and Inclusive Digital Clinical Trial](#) resource demonstrates how digital tools can transform the clinical trials industry.
  1. Learn how different digital tools can be applied to each step of the clinical trial process to optimize efficiencies and improve overall success.
  2. See the digital tools in action with evidenced based resources and references.

The Impact

- The [Diversity, Equity, & Inclusion in Digitized Clinical Trials](#) project resource highlights the power of individual digital tools to address clinical trials challenges.
- Access is a major challenge for clinical trials — both patient access to trials and sponsor access to diverse populations. Digital platforms and solutions will help overcome this challenge.
Sage Bionetworks is a nonprofit health research organization that is speeding the translation of science into medicine. It believes that high-quality, well-annotated data acts as the foundation of modern biomedical innovation. Sage incubates new ways for diverse groups of people to practice research together.

Digital tools give people new ways to share their data, personal stories, and insights with researchers. These tools give voices to participants’ values and choices. We are especially interested in adapting digital tools to support widespread deployment in lower-resource settings.

— Michael Kellen, CTO Sage Bionetworks

The Opportunity

- Sage Bionetworks uses digital platforms and solutions to advance health research.
- Sage Bionetworks develop tools and services that allow researchers to collect digital health measures and monitor the health and well-being of diverse study participants outside the clinic using their smartphones and other remote sensors.

The Resources

The Elements of a Digitized Clinical Trial resource demonstrated the potential of digital tools to transform the clinical trials industry.

1. Learn how each tool can be applied to each step of the clinical trial process to optimize efficiencies and improve overall success.
2. See the digital tools in action with evidenced based resources and references.

The Impact

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource provides details on how digital tools can transform each step of clinical trials process.
- Digital measures can supplement less frequent in-clinic assessments to reveal the ebb and flow of symptoms, better monitor health outcomes in real life, reduce participation burden, and make research access more diverse, equitable, and inclusive.
Digital Assistants can now be safely deployed to build enduring behavior-based human-like relationships that are in compliance with trial protocols, and significantly improve the experience and outcomes for diverse populations.

Conversational AI has come of age!

— Victor Morrison, CSO, Tuzag

The Opportunity

- **Tuzag** is a digital platform for building and nurturing highly interactive enduring relationships using digital assistants that focus on the person not just the patient.

- Tuzag extends the reach, frequency, and capabilities of sites and caregivers with human-like digital assistants that are fully integrated into the sponsor’s trial protocols and can execute proactive and reactive interventions in real-time.

The Resources

- The **Elements of a Diverse, Equitable and Inclusive Digital Clinical Trial** resource demonstrate how digital tools can transform the clinical trials industry.
  1. Learn how a variety of digital tools can be used to increase efficiencies in healthcare or clinical research.
  2. This resource provides examples of additional digital platforms and solutions that can be used to improve health equity.

The Impact

- The **Diversity, Equity, & Inclusion in Digitized Clinical Trials** project resource highlights the power and variety of digital platforms and solutions to address clinical trial challenges.

- The Tuzag digital platform will improve health equity by augmenting the capabilities of sponsors, investigators, and sites.
Real-World Data/Real-World Evidence

Althea.ai

Rubix LS

Considerations for Using RWD/RWE
Partnering with organizations across the continuum of care, Althea.ai delivers predictive analytics through its proprietary AI and ML solutions to help organizations strategically manage patient risk and provide clinically integrated care to improve health equity.

RWD/RWE can help prioritize underrepresented communities for specific diseases and therapeutic areas. Participating on this DiMe project has allowed us to contribute our learnings to these resources.

— Ashish Chaturvedi, CEO, Althea.ai

The Opportunity

Real-World Data/Real-World Evidence can address many challenges facing clinical trials; however, data provenance and integrity must be clear.

The Resources

The resource to guide the Use Real-World Data and Real-World Evidence (RWD/RWE) outlines how this digital tools can increase access to diverse populations.

1. Learn how to identify more and diverse populations at the community and individual levels.
2. Learn how different data sources can be used for advancing health equity.

This resource follows the principles that Althea employs to identify participants for recruitment and retention, and for health data collection and analysis.

The Impact

As outlined by recommendations in the Diversity, Equity, & Inclusion in Digitized Clinical Trials project resources, RWD/RWE can be used to identify diverse populations who can benefit from the treatment and also identify additional information about a participant's life that may impact their participation.
Partnering with organizations across the continuum of care, Althea.ai delivers predictive analytics through its proprietary AI and ML solutions to help organizations strategically manage patient risk and provide clinically integrated care to improve health equity.

**The Opportunity**

- Althea incorporates a single view of Social Inequities, Disease Prevalence, and Clinical Trials across the US to increase access and knowledge for clinical trial designers and implementers.
- These insights enable Althea to help the clinical trial industry unlock better diversity, equity, and inclusion strategies and tactics.

**The Resources**

- The **Market Opportunity Calculator** allows individuals and organizations to build a business case for inclusivity.
  1. Learn about the disease prevalence of specific chronic conditions for diverse populations.
  2. Learn how to use disease prevalence to plot patient engagement.

**The Impact**

- The **Diversity, Equity, & Inclusion in Digitized Clinical Trials** project resource will help identify populations that can benefit the most from a clinical trial, in addition to the use of Althea’s curated dataset to have more diverse, equitable, and inclusive Digital Clinical Trials.

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**RWD/RWE allows us to quantify how different populations are affected and then customize efforts to better serve those populations. This will help the industry address the behavioral and systemic inefficiencies that drive health inequities at every level.**

— Ashish Chaturvedi, CEO, Althea.ai
Using data we can transform outcomes for communities. We have to use technology to understand us [patients], our socio-economic conditions, what's causing us difficulties in why we aren't participating, and leverage data to better understand how to reach communities that have been swept under the therapeutic research spectrum.

— Reginald Swift, Founder and CEO, Rubix, LS

Rubix Life Sciences is wholly focused on changing the nature of life-science research that encompasses precision medical science devoted to inclusive clinical research. Founded in 2016 by Reginald Swift Ph.D, Rubix LS is a digital life research and development company focusing on creating processes and innovations that are focused on patient health and greater patient health outcomes.

The Opportunity

- Rubix LS uses RWD/RWE to fill in knowledge gaps for populations that have been underrepresented in research.
- With these data sources, Rubix LS is using precision data analytics to optimize clinical research for underserved communities.

The Resources

- The resource to guide the Use of Real-World Data and Real-World Evidence outlines how the digital tools of RWD/RWE can increase access to diverse populations and used with AI/ML to increase efficiencies overall.
  1. Learn how to identify more and diverse populations at the community and individual levels.
  2. Use multiple data sources for advancing health equity.

The Impact

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource highlights the need to ensure that all patients are supported in this journey.
- Data sequentialing is used to best represent characterized models for patient data and uncover millions of data streams that overlook under-represented patient information.
Inclusive Engagement

- Acclinate
- Althea.ai
- Amgen
- GSK
- Lightship
- Reveles
- Touch BBCA
- Tuzag

Levels of Engagement

- Support: Advance health equity
- Integrate: Develop trust & build credibility
- Solicit: Empower participants
- Notify: Provide knowledge & resources
NOWINCLUDED is positioned to eliminate historical access and education barriers in the research process by empowering our members to make more informed health decisions, ultimately leading to more inclusive research.

— Shayla Wilson, Head of Community & Digital Engagement, Acclinate

**The Opportunity**

- **Mistrust** has been a key reason for lack of diversity in clinical trials, but by engaging with communities of color and potential trial participants early and often, clinical trial sponsors can develop therapies for all who need them.
- **Successful engagement** requires a detailed diversity plan which includes opportunities to build trust, learn from, and empower communities that have been historically excluded from research.
- Acclinate’s NOWINCLUDED community - which consists of 23,000+ members - helps communities of color engage in and learn about health-related decisions, including decisions around clinical trial participation.
- Through its digital social media platform, email correspondence, and traditional in-person engagement, NOWINCLUDED helps communities of color build relationships, share health-related stories, hear from experts, and encourage one another.

**The Impact**

- Data gathered through initiatives like NOWINCLUDED can be used to inform development of novel therapies for historically underrepresented populations and guide them toward clinical trial opportunities.
- With the Diversity, Equity, and Inclusion in Digitized Clinical Trials inclusive engagement plan, which centers voices and experiences from communities of color, research sponsors can build trust with historically underrepresented communities and increase access to clinical research.
Data analytics enable better patient outcomes through equitable, predictive and personalized healthcare. The path to health equity will require the integration of these digital tools to all aspects of clinical trials, including patient engagement.

— Ashish Chaturvedi, CEO, Althea.ai

Partnering with organizations across the continuum of care, Althea.ai delivers predictive analytics through its proprietary AI and ML solutions to help organizations strategically manage patient risk and provide clinically integrated care to improve health equity.

The Opportunity

- Althea’s built in remote patient monitoring capabilities provide real-time view of trial participants vitals and response to specific actions expected from them.
- Althea drives actionable insights and personalized outcomes for patients by bringing together patients, Healthcare and Life Sciences organizations, including Pharmaceuticals, Payers and Providers, across the entire continuum of care.

The Resources

- The Design an Inclusive Engagement Plan resource provides instructions on designing and implementing an engagement plan with intentionality.
  1. Learn about the different levels of engagement and the benefits of inclusive engagement.
  2. Learn how to identify and engage diverse populations with inclusive measures to ensure all participants can fully participate.

The Impact

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource highlights the importance of continuous engagement and can help teams reduce burdens for participants and clinical trial teams by streamlining and creating efficiencies with awareness and outreach.
There are no quick wins in building a broader clinical trial base. Listening, talking, and actively educating in communities where trial participants live, work, pray, and play and in a way that is both inclusive and targeted are important steps in a long road.

— Racquel Racadio, Director, Representation in Clinical Research, Amgen
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people’s lives.

There are no quick wins in building a broader clinical trial base. Listening, talking, and actively educating in communities where trial participants live, work, pray, and play and in a way that is both inclusive and targeted are important steps in a long road.

— Racquel Racadio, Director, Representation in Clinical Research, Amgen

Amgen understands the critical need for researchers to evolve the way they have traditionally communicated with patients, caregivers, providers, and their larger communities.

For communications to be both inclusive and targeted for specific communities, a thoughtful and comprehensive engagement plan is critical.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people’s lives.

The Opportunity

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For communications to be both inclusive and targeted for specific communities, a thoughtful and comprehensive engagement plan is critical.

The Resources

Design an Inclusive Engagement Plan helps pinpoint how inclusivity meets participants where they are and identifies what they need to participate.

1. Increasing inclusivity in clinical trials offer more knowledge, awareness, efficiencies, outreach, and trust; all critical components of developing a sustainable person-centered process to health equity.

The Impact

Clear communications and an inclusive engagement plan will help to demonstrate the value of participating in a clinical trial to potential participants, their caregivers, their healthcare providers, and their communities, which is critical to successful recruitment and retention and to sustained community relationships.

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource highlights the importance of moving beyond transactional engagement.

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people’s lives.
**The Opportunity**

- In addition to planning for, achieving, and monitoring genomic and metabolic diversity in our study design and execution, GSK recognizes several demographic dimensions within inclusive clinical operations.

- These include (but are not limited to) populations frequently underserved: people with lower socioeconomic status, rural populations, LGBTQIA+ populations, people of all religious beliefs, and those with physical and neurodiverse capabilities.

**The Resources**

- The *Design an Inclusive Engagement Plan* resource provides recommendations on how to design and implement an engagement plan to reach more groups.

  1. Learn about the different levels of engagement and the benefits of inclusive engagement.
  2. Learn how to identify and engage diverse populations with inclusive measures to ensure all participants can fully participate.

**The Impact**

- The *Diversity, Equity, & Inclusion in Digitized Clinical Trials* project resource highlights the importance of continuous engagement.

- Different diseases and medicines can affect people differently depending on their ethnicity, sex, race, and age. So, representing the real-world patient population in GSK clinical trials is important so that GSK data represents real-world outcomes for patients.

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"People can only make a decision when they are aware of a choice. Inclusion starts with making sure everyone knows there are options – it starts with awareness."

— Nisha P. Patel, Engagement Director, Global Demographics and Diversity, GSK
Lightship’s clinical trial partnerships have a purpose: greater patient access. By focusing on moment-to-moment flexibility and a simplified user experience, Lightship puts people at the heart of clinical research. We embrace the latest patient-centric technologies and modalities to deliver safe and effective therapies to a more diverse patient population.

Lightship’s specialized patient engagement teams design inclusive and adaptable outreach strategies customized for success within each patient community.

Lightship’s clinical trials are easily accessible, offering more choice and greater flexibility to patients in need. By engineering research environments to be more accepting and user-friendly toward trial participants, Lightship can bring better therapies to people faster.

When I think about digital technology and designing a study, it’s important to get patient, caregiver, and family member insights and feedback, and to plan for infrastructure to support patients in their journey across that trial.

— Sam Eells Co-Founder, Lightship

With the Plan for Diverse, Equitable, and Inclusive Engagement resource teams can implement outreach and engagement strategies that are inclusive and effective.

1. Learn how to reach different and multiple populations for sustained engagement and participation.
2. Learn the benefits of inclusive engagement and the value it brings to your trial.

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource will help to increase access to clinical trials for patients, while exposing sponsors to more diverse populations.

By demonstrating a genuine interest in diverse populations, the clinical trials industry can begin to build a community of trust for broader trial participation in the future.
Lightship’s clinical trial partnerships have a purpose: greater patient access. By focusing on moment-to-moment flexibility and a simplified user experience, Lightship puts people at the heart of clinical research. We embrace the latest patient-centric technologies and modalities to deliver safe and effective therapies to a more diverse patient population.

Lightship provides a dedicated patient engagement team to every study. This team’s mission is to cultivate a research environment of persistent engagement that speaks to every participant.

Lightship’s clinical trials are easily accessible, offering more choice and greater flexibility to patients in need. By designing trials to be more accepting and user-friendly toward participants, Lightship brings better therapies to people faster.

The Design an Inclusive Engagement Plan resource provides instructions on designing and implementing an engagement plan with intentionality.

1. Learn about the different levels of engagement and the benefits of inclusive engagement.
2. Learn how to identify and engage diverse populations with inclusive measures to ensure all participants can fully participate.

The Impact

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource provides greater access to diverse patients for clinical trial sponsors while increasing awareness and access to clinical trials for patients.

By demonstrating a genuine interest in diverse populations, the clinical trials industry can begin to build a community of trust for broader trial participation in the future.

When designing a study, it’s important to understand what each person needs to stay engaged and be successful. You have to get patient, caregiver, and family member insights.

— Sam Eells Co-Founder, Lightship
Reveles Clinical Services is a purposeful, Decentralized Clinical Trial Management company that aims to eliminate zip code from being a barrier to participating in clinical trials for all patients. For biopharma, diagnostics, digital health, and CROs, Reveles closes the access gap and accelerates the clinical trial process by enabling patients to participate from the comfort of their homes.

Reveles’ mission of Bringing Hope Closer To Home™, recognizes how critical inclusive engagement is for increasing clinical trial awareness and expanding access to all populations who can benefit.

Clinical trials success is closely tied to patients feeling included and heard throughout the clinical trial process. Reveles’ DCT model aims to make clinical research more patient-centric.

The Opportunity

The Resources

The Design an Inclusive Engagement Plan resource provides instructions on designing and implementing an engagement plan that serves the people who need to participate in clinical trials.

1. Learn about the different levels of engagement and the benefits of inclusive engagement.
2. Learn how to identify and engage diverse populations with inclusive measures to ensure all participants can fully participate.

The Impact

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource gives a voice to patients and moves away from transactional to sustained engagement.

Participants need to be engaged throughout the clinical trial process, not only at enrollment.

We have an unwavering mission and commitment to address the underrepresentation and lack of diversity of geographical, age, ethnic, and racial minorities by increasing awareness and expanding access to groundbreaking clinical research. We can do this by acknowledging the impact of cultural values on the decisions made by people of color in individual, communal, and international contexts.

— R’Kes Starling, CEO, Reveles Clinical Services
The Black Breast Cancer Alliance drives the collaborative efforts of patients, survivors, advocates, advocacy organizations, health care professionals, researchers and pharmaceutical companies to work collectively, with accountability, towards the common goal of eradicating Black Breast Cancer.

You cannot just use images of black and brown people to get traffic to your website. If you want people to trust you and believe that you have their best interest at heart when you ask them to join your trial, you have to be intentional and show that you will dedicate time to get to know and understand their health needs.

— Ricki Fairley, CEO and Co-Founder, TOUCH

The Opportunity

- Digital tools provide the opportunity to meet more and diverse patients. Intentional efforts, demonstrating a real understanding of patients and their communities are needed when using digital campaigns and social media.
- It is not enough to use a Black woman on the cover of the add for a trial. A narrative is needed which shows deep and real understanding of her lived experiences before she is asked to join a trial.

The Resources

- The Plan for Diverse, Equitable, and Inclusive Engagement resource outlines how to engage diverse populations and ensure that they feel heard and represented.
  1. Develop inclusive and engaging outreach for retention and support.
  2. Learn how to reach different and multiple populations for sustained engagement and participation.

The Impact

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource highlights the importance of continuous and respectful engagement.
- A true representation in engagement materials will help to build trust and demonstrate commitment from the clinical trials industry to be more equitable and inclusive.
A large number of DEI focused community organizations empowered with the ability to offer an advanced conversational AI platform that builds holistic trusted and personalized relationships with millions of potential trial participants that have been recruited, profiled, and primed for successful participation in clinical trials.

More efficient, effective, and accessible trial protocols with integrated behavior-based human-like digital assistants trained to augment site capabilities. 24/7 access to a personalized concierge, companion, coach. Continuously tracking of wearables, efficacy, symptoms, SEs, and AEs. Connected to curated protocol approved local and national services and resources.

A trusted personalized relationship is critical for successful DEI recruiting and RWE clinical trials. Our Digital Assistant platform builds human-like trusted relationships and enables behavior-based real-time interventions...all within the context of trial protocols and stringent medical-legal-regulatory frameworks. — Neal A Sofian, CEO, Tuzag
Empower Participants

- Amgen
- Lightship
- Medable
- Sage Bionetworks
- Touch BBCA
- Tuzag

Inform and Educate
Demystify Clinical Trials
Tackle the Digital Divide
The Opportunity

Part of bringing research to where potential participants live, work, pray, and play includes using resources that take advantage of digital tools for education, awareness, and even participating in research itself.

The Resources

- Learn the importance of educating and empowering participants in clinical trials with the Amgen Empower With Information and Education resource.
  1. Ensuring all participants have the tools and resources needed increases trust and engagement for improved retention.
  2. Tools are provided to help clinical trial teams develop educational and training materials.

The Impact

- The Amgen Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource aims to bridge the digital divide and meet patients where they are so they can fully participate.
- Amgen is bridging the digital divide and thoughtfully and inclusively using technology that has the potential to drastically improve the recruitment and retention of diverse and representative participant populations.

Ensuring that we are bridging any digital divides in terms of access, user experience, and relevance and that we are using technology thoughtfully and inclusively, and have the potential to drastically improve the recruitment and retention of diverse and representative participant populations; that’s something we are really excited about.

— Racquel Racadio, Director, Representation in Clinical Research, Amgen
Lightship’s people-first approach to clinical trial design and execution makes it easier for patients and caregivers to become an active part of clinical research. By offering more options for participation and harnessing the most cutting-edge technologies in patient engagement and data analysis, we create inclusive clinical trials that deliver more life-saving therapies to those in need.

Digital tools can make it easier to participate in clinical trials. eConsent simplifies the process for both the patients and the decentralized clinical trials team.

— Sepehr Shojaei  Vice President, Design Solutions, Lightship

**The Opportunity**

- Lightship designs clinical trials to encourage easy and convenient participation while satisfying each study milestone. Lightship’s inclusive delivery models provide at-home and near-home flexibility for every step of the process, including informed consent.

- Lightship leverages Lightship’s preferred eConsent providers to create a fast and user-friendly experience.

**The Resources**

- The Empower Through eConsent resource provides instructions on developing an interactive consenting process with transparency and clarity.
  1. Learn the value and benefits of using digital tools to engage, inform, and enroll diverse participants.

**The Impact**

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource will ease the consenting process for sites/patients and provide options for remote consenting.

- The undeniable efficiencies of eConsent increase patient engagement and improve overall retention.
Lightship’s clinical trial partnerships have a purpose: greater patient access. By focusing on moment-to-moment flexibility and a simplified user experience, Lightship puts people at the heart of clinical research. We embrace the latest patient-centric technologies and modalities to deliver safe and effective therapies to a more diverse patient population.

Digital technology has completely transformed the way we do clinical trials. Accessibility and ease-of-use must be considered down to the specific individual and how their reactions might influence compliance.

— Sam Eells Co-Founder, Lightship

The Opportunity

- Lightship’s people-first approach places a lot of emphasis on patient choice. However, the freedom of patient choice can only be enjoyed when that patient is fully educated on their options.
- Our goal is to make clinical trials open and accessible. Every design choice or delivery method is selected with the patients and professionals in mind. By educating patients on the process, we make choice more meaningful and deliver more therapies to market.

The Impact

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource will help you ensure that patients have all the support they need to fully participate.
- Greater access and more widely available knowledge means clinical trials are more inclusive. Greater inclusion means trials and their innovations are better ready to serve every patient.

The Resources

- This resource outlines how to Empower Participants with Information and Education. Such efforts can be the difference between retention and re-recruitment—between inclusion and exclusion. You’ll learn:
  1. How to bridge the digital divide and demystify the clinical trial process.
  2. How to develop informational materials and training sessions for patients.
eConsent is a scalable and flexible approach to streamline the consenting process. The process becomes more interactive and allows for engaging more diverse populations.

eConsent incorporates a variety of communication channels to provide greater participant engagement and content recall. Medable has developed eConsent solutions for better participant access and experience.

The Opportunity

Work with the project team highlights the opportunities for digital tools to advance health equity. One example is embedding commonly used approaches such as videos to facilitate better understanding of study tasks and help potential participants provide truly informed consent.

— Ingrid Oakley-Girvan, Senior VP of Strategy and Value, Medable, Inc.

The Resources

The Empower Through eConsent resource provides instructions on developing an interactive consenting process with transparency and clarity.

1. Learn the value and benefits of using digital tools to engage, inform, and enroll diverse participants.

The Impact

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource provides additional opportunities to engage and educate patients.

The eConsent allows for increased access to diverse participants and streamlined workflows for participant enrollment.
Sage Bionetworks is a nonprofit health research organization that is speeding the translation of science into medicine. They believe that high-quality, well-annotated data acts as the foundation of modern biomedical innovation. They incubate new ways for diverse groups of people to practice research together.

Sage Bionetworks developed an interactive participant-centric informed consent (eConsent) experience for participation in remote app-mediated research studies.

Through the “Empower Through eConsent” resource, they share best practices for developing a more engaging, meaningful, and effective consenting process.

The Resources

- The Empower Through eConsent resource provides instructions on developing an interactive consenting process with transparency and clarity.

The Impact

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource emphasizes opportunities to engage and inform participants for more robust outcomes.

- eConsent is an attractive learning experience that can address comprehension challenges, reach a broader range of people interested in research, and engage those traditionally excluded from participating in research.

- A well-designed eConsent can help scale and diversify research participation by bringing research to people and allowing time for reflection without the pressure and inconvenience of being in a clinic environment.

- eConsent can support the autonomous decision of diverse populations with a wide range of cognitive abilities and lived experiences.

- eConsent can acquire the rights needed to allow secondary reuse of data for other research purposes, inline with the wishes of most participants.

— Christine Suver, PhD, VP Research Governance, Sage Bionetworks

The Opportunity

- Sage Bionetworks is enthusiastic about leveraging digital technology to create self-paced participant-centric eConsent experiences that engage and educate people about biomedical research. We strengthen the informed consent process by fostering understanding and focusing on protecting vulnerable populations, building trust, and making research participation more diverse and equitable.
Black women need to know that our breast cancer deserves special attention and we all together, need to advance the science. This is a call to action for our fierce resilient community of black women. We have to advocate for ourselves and each other in order to get access to a better black standard of care.

— Ricki Fairley, CEO and Co-Founder, TOUCH
The Opportunity

- **Tuzag** is a digital platform for developing and optimizing highly interactive, conversational AI digital assistants that see someone as a person first who is sometimes a patient.
- As an omni-channel engagement platform, Tuzag aims to develop a holistic continuum of care.

The Resources

- The resource to **Empower Participants with Information and Education** will support all populations, including those underrepresented or underserved by healthcare, to learn more about their health and the healthcare system.
  1. This resource shows you how to bridge the digital divide and demystify complex clinical processes.
  2. Use this resource to develop informational materials and training sessions for patients.

The Impact

- The **Diversity, Equity, & Inclusion in Digitized Clinical Trials** project resource help ensure that patients have all the support they need to fully participate.
- Tailored interventions and engagement is critical for wellness and behavioral health.

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**We have a lot of ground to make up with people of color! It is imperative that our digital platforms and resources prioritize diversity, equity, and inclusion. DiMe has assembled the best possible repository of resources.**

— Victor Morrison, CSO, Tuzag
Build Trust & Support Teams

- Acclinate
- Amgen
- GSK
- Inlightened
- Lightship
- Touch BBCA

Build Trust & Credibility

- Community Partnerships
- Representative Clinical Teams
- Participant Support Network
Communities of color are still suffering from a lack of trust in the healthcare system, misinformation and limited access. Partnering with existing trusted leaders and community-based organizations allows us to build a sustainable community. We believe this is the best approach to closing the health disparity gap – by transferring health information faster and broader, while prioritizing trust.

— Tiffany Whitlow, Co-Founder & Chief Development Officer, Acclinate

Research sponsors must **collaborate with trusted community leaders and partners** to build genuine relationships with populations historically underrepresented in clinical research.

These partnerships should be **mutually beneficial** and are vital for understanding cultural norms, educating potential trial participants, enhancing trust, and ensuring clinical trial success.

Acclinate leverages its **Community Activation Points**, which are individuals and organizations with credibility and influence within communities of color, to develop and maintain such partnerships.

Community Activation Points serve as trusted messengers, reflective of community demographics, who can amplify the message regarding the importance of clinical research and opportunities to participate.

By leveraging the [Diversity, Equity, and Inclusion in Digitized Clinical Trials](#) project’s guide to developing community partnerships, industry stakeholders can accelerate changes to improve health equity and overall efficiencies of clinical trials.
Trust is the cornerstone of clinical trials. Change will only occur if there is a collective willingness to learn, to commit, and to take action. A key part of that action is ensuring that our community relationships are not only genuine, but sustainable for the long term.

— Jude Ngang, Executive Director, Representation in Clinical Research, Amgen
Without focusing on inclusion across the clinical research ecosystem, we’re only addressing a portion of the issue. To truly advance health equity, representation in clinical research begins with participants, but it also extends to health care providers, clinical trial investigators, and clinical site staff, who should also be representative of the communities we are trying to reach.

— Jude Ngang, Executive Director, Representation in Clinical Research, Amgen
Doctors and their patients look to make sound medical decisions based on data. Our job is to ensure our studies represents the patient as early and as accurately as possible.

— Michel Reid, Sr. Director and Head, Global Demographics & Diversity, GSK
Working with a healthcare provider that inherently understands a lot about you carries an important foundational trust for everyone, but especially in historically underserved communities.

— Michel Reid, Sr. Director and Head, Global Demographics & Diversity, GSK

GSK is a global biopharma company with a purpose to unite science, technology and talent to get ahead of disease together. We aim to positively impact the health of 2.5 billion people over the next 10 years. Our bold ambitions for patients are reflected in new commitments to growth and a step-change in performance.

GSK’s commitment to increased diversity also extends to clinical trial researchers. GSK has demonstrated this commitment by funding STEM programs to help Black, Latinx, and female students overcome obstacles as they pursue careers in science, technology, engineering, and mathematics.

GSK is developing a diverse pool of investigators and equipping staff with cultural competence to engage with communities and advocacy groups to build trust, enhance awareness and provide information, education and outreach.

The opportunity

The resources

The impact

The resource Diversify Clinical Teams to Build Trust provides recommendations on how to engage and support diverse clinical trial investigators and other clinical trial study personnel.

1. Learn how about the benefits of diverse clinical investigators and teams.
2. Learn how digital tools can be used to improve representation of clinical trial principal investigators and site teams.

The Diversity, Equity, & Inclusion in Digitized Clinical Trials resource demonstrates the great need for diversity with all members of the clinical trial team.

Resources to help diversify clinical trial researchers early in their careers will lead to increased diversity overall and help advance health equity.
GSK is a global biopharma company with a purpose to unite science, technology and talent to get ahead of disease together. We aim to positively impact the health of 2.5 billion people over the next 10 years. Our bold ambitions for patients are reflected in new commitments to growth and a step-change in performance.

The Opportunity

- GSK partnered with MiOra, a Los Angeles-based non-profit organisation whose mission is to improve public health while increasing the diversity in healthcare and STEM fields by supporting high school and college students from socioeconomically challenging backgrounds.

- Through the partnership, GSK supported MiOra’s Improving the Diversity in Cancer Clinical Trial Program and trained eight California State University public health school students as community health educators with a focus on three ontologies with disparate outcomes within the African American, Latinx and older communities: ovarian and endometrial cancer and multiple myeloma.

The Impact

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials resource aligns with GSK’s objective to build disease awareness, enhance understanding of the value of clinical research, and build trust at the community level with GSK’s commitment to bringing first-class oncology research to patients with significant unmet need.

- Students organized outreach efforts to understand the awareness and attitudes of minority women on Ovarian Cancer in Los Angeles County. They educated 331 Black and Latino women and conducted surveys to understand the impact of their efforts and the needs.

People trust information when it comes from experts from their communities. This program helps to educate future scientists who are already giving back to their communities.

— Nisha P. Patel, Engagement Director, Global Demographics and Diversity GSK
GSK is a global biopharma company with a purpose to unite science, technology and talent to get ahead of disease together. We aim to positively impact the health of 2.5 billion people over the next 10 years. Our bold ambitions for patients are reflected in new commitments to growth and a step-change in performance.

If we conduct our operations in a way that is inclusive and appropriate and we handle the humanity of it, everyone benefits.

— Michel Reid, Sr. Director and Head, Global Demographics & Diversity, GSK

GSK provides training and support to our research collaborators for success in enrolling diverse populations. The clinical trial process is complex and comes with many challenges. An important component of our commitment to diversifying clinical trials is providing the training and support that our teams need to better serve our participants.

The Opportunity

The Resources

The resource **Support and Train Clinical Trial Site Staff** provides recommendations on supporting clinical trial teams.

1. The resource shares how to set clinical site teams up for success and alignment with sponsor diversity goals.
2. The resource provides trainings and guides that sponsors can use to create training plans for digitized clinical trials and diversity.

The Impact

The **Diversity, Equity, & Inclusion in Digitized Clinical Trials** project resources can impact the overall success of clinical trials.

Sustained support for all stakeholders in the clinical trial process can lead to increased diversity and overall clinical trial success.
The resource Diversify Clinical Teams to Build Trust highlights the great need for diversifying clinical trials investigators and clinical trial personnel.

1. Learn how digital tools can be used to improve representation of clinical trial principal investigators and site teams.
2. Learn how about the benefits of diverse clinical investigators and teams.

Inlightened offers clinical trial sites and sponsors transparency, diversity, and a wide depth and breadth of expertise to facilitate engagement with the investigators who can most effectively move trials forward.

Data has shown that diversity of staff at investigator sites leads to greater participation by more minority patients in clinical trials — a healthcare innovation that can help fix the broken process plagued by a lack of access, diversity, and transparency. In this instance, seeing is believing.

— Michelle Higginson, COO & Co-Founder, Inlightened

Inlightened is passionate about optimizing healthcare innovation for all. The Inlightened platform democratizes access to the only marketplace of curated, vetted, and engaged clinicians and healthcare professionals, passionate about shaping the future of their fields.

The Impact

The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource reinforces the need for staff diversity.

Diverse clinical staff is a key element for a future clinical trials industry where diversity, equity, and inclusion are inherent to all clinical trials.
One reason for lack of diversity among clinical investigators is limited information on how to run clinical trials, and lack of access to opportunities. The ever-growing collection of digital health technologies adds a layer of complexity.

Clinical investigators need ongoing support and resources to better execute clinical trials and serve participants, facilitating rather than burdening their participation. Inlightened supports feasibility questionnaires, pre-study documentation completion, scheduling, time tracking, and compensation so personnel can focus their energy on the task at hand.

The resource **Support and Train Clinical Trial Site Staff** provides recommendations on supporting clinical trial teams.

1. Learn how to set clinical site teams up for success and alignment with diversity goals.
2. Use these resources to create training plans for digitized clinical trials and diversity.

The **Diversity, Equity, & Inclusion in Digitized Clinical Trials** project resource brings attention to the value of supporting all stakeholders for success.

Resources to support clinical trial investigators and teams will be valuable with streamlining workflows and increasing clinical trials efficiencies.

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Inlightened is passionate about optimizing healthcare innovation for all. The Inlightened platform democratizes access to the only marketplace of curated, vetted, and engaged clinicians and healthcare professionals, passionate about shaping the future of their fields. The SaaS provider’s technology effectively eliminates the administrative burden — with unprecedented transparency, and automated vetting, contracting, scheduling, and payment — so members can focus on the task at hand: Disrupting responsibly.

**Clinical research has long been burdened by complex technology and barriers to entry, for diverse investigators and patients alike. Inlightened is committed to breaking these bottlenecks.**

— **Shelli Pavone** CEO & Co-Founder, Inlightened
Lightship’s clinical trial partnerships have a purpose: greater patient access. By focusing on moment-to-moment flexibility and a simplified user experience, Lightship puts people at the heart of clinical research. We embrace the latest patient-centric technologies and modalities to deliver safe and effective therapies to a more diverse patient population.

Lightship aims to empower patients with more access and more choice. Community partnerships are an invaluable resource in making it easier for people to find, join, and take part in clinical trials.

— Sam Eells  Co-Founder, Lightship

The Opportunity

» Lightship is part of a powerful group network whose goal is to identify and cultivate targeted community partnerships throughout the clinical research space.

» Lightship’s clinical trials are built their communities, offering more choice and greater flexibility. By engineering research environments to be more attractive and accepting to trial participants, Lightship delivers more therapies to market.

The Resources

» This Guide to Develop Community Partnerships is supported by the principle that every effort to increase equity and inclusion in clinical trials starts with building community trust. You’ll learn:
  1. The importance of community partnerships and their unique benefits for improving clinical trials.
  2. Every step to identifying and developing strong community partnerships using advanced digital tools.

The Impact

» The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource will increase awareness and access to clinical trials for diverse populations.

» By demonstrating a genuine interest in diverse populations, the clinical trials industry begins to build a community of trust for broader trial participation in the future.
Lightship’s people-first approach to clinical trial design and execution makes it easier for patients and caregivers to become an active part of clinical research. By offering more options for participation and harnessing the most cutting-edge technologies in patient engagement and data analysis, we create inclusive clinical trials that deliver more life-saving therapies to those in need.

Navigating clinical trials can be overwhelming. Patients and professionals need support with digitization throughout the life of the clinical trial.

— Sepehr Shojaei, Vice President, Design Solutions, Lightship

**The Opportunity**

- Streamlining the digital process and increasing trial efficiencies includes dedicating new or current team members to the incorporation of the latest digital tools.

- By utilizing our technology platforms and people-first approach to clinical research, Lightship ensures that sites and investigators can participate in more studies and engage with more patients, while still maintaining their current practice. A dedicated digital navigator makes it all possible.

**The Resources**

- The [Digital Clinical Trials Navigator](#) resource is a job description detailing how this role can set clinical trials up for success and keep sponsors on track with their diversity plans.

1. Learn how a digital clinical trials navigator can support clinical trial teams and participants.
2. Customize the job description to include this role from the sponsor, CRO/DCT or site level.

**The Impact**

- [The Diversity, Equity, & Inclusion in Digitized Clinical Trials](#) project resource allows hiring and onboarding of study teams who are capable of operating innovative and digitized trials.

- This resource emphasizes the importance of digitization and provides trusted support.
Touch, The Black Breast Cancer Alliance drives the collaborative efforts of patients, survivors, advocates, advocacy organizations, health care professionals, researchers and pharmaceutical companies to work collectively, with accountability, towards the common goal of eradicating Black Breast Cancer.

Patients and their families need support from the industry and from our communities. The thought of a clinical trial can be scary. But without our participation in clinical research, Black women are missing out on access to the newly emerging and often life-extending treatments that could save us. Until we have more Black women included in research, we cannot put an end to the disparities that Black breasties face.

— Ricki Fairley, CEO and Co-Founder, TOUCH

The Opportunity

» Touch, the Black Breast Cancer Alliance is committed to providing a strong support network for BREASTIES and their communities.

» This type of support is invaluable as patients participate in clinical trials. Digital platforms can be used to provide support to patients from across the country, and the clinical trials industry should supplement the work being done by patient advocacy groups.

The Resources

» The resource on how to Develop a Virtual Participant Support Network to Build Trust emphasizes why and how all clinical trial participants should be heard and supported.

1. Learn how to support patients through their clinical trial journey; this can be vital for bridging the gaps created by mistrust and lack of knowledge that have resulted in underrepresentation of diverse populations in clinical trials.

The Impact

» The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource highlights the need to ensure that all patients are supported in this journey.

» Support networks will build trust and provide a community where clinical trial participants can learn, grow and feel heard. This will go a long way with patient retention and improve clinical trial outcomes.
Accountability

- Acclinate
- Amgen
- Lightship
- Reveles
- Rubix LS
- Touch BBCA

Promote Accountability

1. Analyze Historical Data
2. Collect and Analyze Prospective Data
3. Standardize Data Analysis
4. Share Data Publically
E-DICT gives sponsors, CROs, and sites the ability to track and report key community engagement KPIs that correlate to diverse patient recruitment and provides community analytics to assess spend and efforts. The result is an industry-leading tool for enabling sponsors, CROs, and sites data-driven decisions to optimize their recruitment strategies and assess ROI.

— Del Smith, Co-Founder & CEO, Acclinate

The Opportunity

» The clinical trials industry needs specific metrics to benchmark and assess performance their efforts to make critical adjustments for increasing diversity in clinical trials.

» Acclinate's e-DICT is a patent-pending analytics tool that leverages AI and machine learning to evaluate engagement within Acclinate's NOWINCLUDED community to determine which members are most likely to participate in clinical trials.

» Acclinate's Participation Probability Index (PPI) generated through e-DICT's algorithm allows research sponsors to see real-time reports and provides qualified participant leads for initial screening and enrollment of trials.

» Using PPI aggregate-level data can also be used to guide trial site identification and selection in communities where there is higher likelihood of participation willingness.

The Impact

» As recommended by Diversity, Equity, and Inclusion in Digitized Clinical Trials project, a Diversity Dashboard measuring success and demonstrating accountability with the development and use of standardized metrics will reinforce and emphasize the efforts made to advance health equity.
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives.

Amgen is dedicated to an evidence-based, data-driven strategy to improve diversity and representation in clinical trials. We seek to continually evolve that strategy, incorporate best practices, and ensure our own transparency as an industry sponsor of clinical research.

— Racquel Racadio, Director, Representation in Clinical Research, Amgen

**The Opportunity**

- Amgen is committed to developing sustainable infrastructure to support diversity and representation in clinical trials, both internally and externally.

- As part of that commitment, Amgen has created a participant diversity dashboard which allows for tracking and reporting clinical trial participant demographic data historically and in real-time.

**The Resources**

- The **Design a Diversity Dashboard** resource encourages sponsors to demonstrate their commitment and hold themselves accountable for quantifying and improving diversity efforts.

  1. Learn the importance of utilizing a diversity dashboard and the potential impact.

  2. Develop a system with metrics to ensure that diverse participant enrollment goals are met.

**The Impact**

- The **Diversity, Equity, & Inclusion in Digitized Clinical Trials** project resource is encouraging more public accountability from the clinical trials industry to improve diversity.

- Amgen seeks to continually improve and incorporate best practices as well as ensure transparency as an industry sponsor. These recommendations will help Amgen to further refine this dashboard.
Lightship believes clinical research can improve health equity around the world. By expanding on trial accessibility and offering greater patient choice, we can quickly identify safe and effective treatments for those in need. People are at the heart of everything we do, and we use the most advanced digital tools and latest remote care innovations to support greater diversity and broader participation in clinical trials.

If we commit to more diversity and inclusion, clinical research can affect health equity around the world. Through this project, we partnered with fellow industry leaders devoted to the very same mission.

— Sam Eells Co-Founder, Lightship

The Opportunity

- We work with sponsors to build customized key performance indicators and dynamic data dashboards to monitor and respond to diversity metrics. These proactive measures represent the future of equity in clinical research.

- This future is a team effort. Lightship is focused on solving one of the longest-standing challenges in research: trial access. By embracing a people-first approach to study design and execution, we make equity a priority.

The Resources

- These recommendations for a Diversity Dashboard help you create a focal point for your diversity efforts to better measure and define their success. You’ll learn:

  1. How to use digital tools to identify, collect, and quantify diversity metrics.

  2. The value of demonstrating accountability and the impacts of advancing health equity.

The Impact

- The Diversity, Equity, & Inclusion in Digitized Clinical Trials project resource allows industry leaders to demonstrate their commitment to promoting greater equity in clinical research.

- This commitment demands sustainable mechanisms for improving the trial process overall, while cultivating more diversity, equity, and inclusion across the industry.
The Opportunity

- 44.24%: By the year 2030, the population of BIPOC communities in the United States is projected to represent 44.24 percent.
- 84%: 84 percent of people of color make up the worldwide majority, while caucasian communities only account for 16 percent.
- 80% - 90%: However, a large majority of those taking part in clinical trials for new medications are disproportionately Caucasian - sometimes as much as 80 to 90 percent.

The Impact

- The recommendations for a Diversity Dashboard is a call to action for all in the clinical trials industry: it's time to show accountability.
  1. Start with examining your historic data on patient enrollment and retention.
  2. Develop a mechanism to capture and measure your efforts to more diverse, equitable, and inclusive.

We need to create a world where knowledge is accessible, understanding is shared, and the power of science is embraced. Together, we can unlock a future full of possibility and hope. That starts with all stakeholders at the table, holding each other accountable.

— R’Kes Starling, CEO, Reveles Clinical Services
Rubix Life Sciences (Rubix LS) is wholly focused on changing the nature of life-science research that encompasses precision medical science devoted to inclusive clinical research. Founded in 2016 by Reginald Swift Ph.D, Rubix LS is a digital life research and development company focusing on creating processes and innovations that are focused on patient health and greater patient health outcomes.

Minority populations could significantly benefit from inclusion in clinical trials and resulting innovations. Additional effort must be placed upon clinical trial recruitment to address whether the findings from clinical trials will be generalizable to minority populations.

— Reginald Swift, Founder and CEO, Rubix, LS

The clinical trials industry recognizes that lack of diverse participants is a problem. With demonstrated accountability there is the opportunity to collect more information and allocate resources to areas with large knowledge gaps.

The cold statistics are concerning. For example, there are clear and alarming disparities in clinical trial participation among different populations. African Americans represent 5% of clinical trial participants but constitute 12% of the United States population; Hispanics make up 1% of participants, but 16% of the people

The recommendations for a Diversity Dashboard is a call to action for all in the clinical trials industry to show accountability.

1. Start with examining historic data on patient enrollment and retention.
2. Develop a mechanism to capture and measure efforts for more diverse, equitable, and inclusive.
Our work requires partnership, shared resources and knowledge, and consistent action so that we can hold each other accountable towards advancing critical, life-saving science for Black breast cancer survivors/thrivers. Accountability is critical to advancing health care and especially with developing the life saving treatments that are desperately needed.

— Ricki Fairley, CEO and Co-Founder, TOUCH