

EMD Serono Quantifies Progress Across its Organization Using CTTI's Diversity Maturity Model

EMD Serono Leverages CTTI's Recommendations for Increasing Diversity in Clinical Trials

SUMMARY

Historic and continued underrepresentation of racial minorities, ethnic minorities, and women in U.S. clinical trials has limited our knowledge of medical products' safety and efficacy, leaving us with decreased generalizability and confidence in the results for underrepresented populations. CTTI's Increasing Diversity in Clinical Trials [recommendations](#) and [a maturity model](#) were designed to support organizations that design and conduct clinical trials in addressing this challenge. They offer tips and a tool to help stakeholders develop, evaluate, and improve key organizational-level practices to increase the inclusion of diverse patient populations across their clinical trials. This case study shares EMD Serono's experience using these recommendations and maturity model to 1) build greater diversity, equity and inclusion (DE&I) into every phase of its research and development (R&D) processes and 2) capture metrics to assess meaningful progress against its goals.

GOAL(S)

There is no time to waste when it comes to augmenting DE&I in meaningful ways across the clinical trials ecosystem. Trials that underrepresent diverse populations have too long created knowledge gaps about the risks and benefits of drugs and devices for the public. Recognizing the urgency to address these gaps, the U.S. Food and Drug Administration (FDA) now recommends that sponsors include an [action plan to increase diversity](#) when proposing clinical trial designs for investigational products.

But integrating a measurable, effective DE&I action plan across a broad, global organization is easier said than done. Coordinating efforts to ensure consistent and meaningful change across a global company like EMD Serono (which is the healthcare business of Merck KGaA, Darmstadt, Germany in the U.S. and Canada) requires thoughtful consideration of the nuances in how global cross-functional teams and geographically diverse sites operate. Even with the best intentions, familiar patterns in ways of working can be hard to break as the organization works to collectively move the needle on DE&I. At the same time, the FDA guidance gives investigators and sponsors quite a bit of freedom in determining what methods will help them reach their diversity goals; that freedom can be overwhelming when trying to operationalize an organizational action plan. This case study explores how EMD Serono's Head of In Country Clinical Operations Americas worked alongside the company's Strategic Initiative Co-Lead for Sustainability in Healthcare R&D to successfully bring an effective DE&I action plan to life.

CHALLENGES

EMD Serono had created a clinical trials strategy to integrate DE&I meaningfully across its organization, but it needed to create a standard DE&I measure of progress. This is a common challenge; when it comes to DE&I program implementation, the struggle to connect the dots between best intentions and tangible results is real. Since DE&I in clinical trials is multifaceted, any effort to measure its implementation success must be multifaceted, too. EMD Serono needed a tool that could help them measure the various dimensions of DE&I success in a tangible, standardized, and actionable way.

SOLUTION(S)

EMD Serono's Head of In Country Clinical Operations Americas had experience working with CTTI on its Increasing Diversity in Clinical Trials project team, so she was a step ahead when it came to best practices for DE&I measurement in clinical research. CTTI's [recommendations](#) and [maturity model](#) were designed to help stakeholders adopt new or improve existing organization-level practices that increase diversity in clinical trials, leading to enriched research results that are more relevant for everyone - exactly what EMD Serono was seeking. Of particular interest was CTTI's [Diversity Maturity Model for Organizational Strategies](#), which offers a framework for measuring the different dimensions of DE&I integration across an organization. This resource would be the model that would ultimately guide EMD Serono in building its own DE&I measurement tool aligned to the needs of its organization. In addition, the measurement is integrated in the harmonized Healthcare R&D Design for Sustainability framework where other sustainability areas, including Green Chemistry and Animal Welfare, are assessed.

TAKING ACTION

EMD Serono customized CTTI's Diversity Maturity Model to align with the organization's structure and goals, involving cross-functional collaboration across R&D. The Head of In Country Clinical Operations Americas and Strategic Initiative Co-Lead for Sustainability identified different facets of DE&I integration based on a landscape and literature analysis and adapted the maturity model content accordingly to develop a Diversity, Inclusion and Equity in Clinical Trials Scorecard. Ultimately, they agreed to score efforts across four domains:

1. Culture and Leadership
 - Leadership support
 - Accountability
 - Dedicated personnel
2. Disease Strategy
 - Epidemiological analysis
 - Statistical planning
 - Community and patient engagement
3. Program Strategy

- Analytical strategy
- Study design development
- Operational strategy
- Site feasibility

4. Impact and Value

- Lessons learned
- Continuous improvement metrics

Design for Sustainability Diversity, Equity, and Inclusion Scorecard

The Development



These elements are the foundation of the creation of the Scorecard

The Breakdown



EMD Serono assigns an analyst/owner to each category who is the ultimate decision-maker on the score, but the process is deeply collaborative. Each owner brings in cross-functional perspectives from across the program or asset via a diversity scorecard evaluation workshop before ultimately landing on a score for a given category, documenting the rationale for the score. Any gaps and recommended actions are also documented.

Prior to the roll-out phase, leaders aligned to keep teams accountable for progress. The successful tracking of and engagement in the assessments is also tied to company rewards. This allowed the evaluation process to be strategically embedded within Program teams to ensure leadership support and drive the integration of DE&I. Because the model was not solely focused on the end results of clinical trials, but rather the implementation of principles that could drive meaningful change, EMD Serono was able to set targets and encourage progress without penalization. An automated scoring app was developed to streamline the evaluation process to consistency while facilitating quarterly progress reviews, and the entire process was tested and refined by "sprint pilots" prior to broader adoption across the organization.

IMPACT

EMD Serono's proactive approach to implementing its own Diversity Maturity Model demonstrated a commitment to driving meaningful change that was acknowledged across the organization. By creating a standardized and customizable framework, the organization not only addressed the challenge of measuring DE&I, but also raised awareness and accountability for everyone. At the time of this writing, the model's implementation is new, and scoring has not yet been tracked over time. However, its implementation team plans to track findings quarterly and feels confident in the model's ability to standardize and measure EMD Serono's DE&I journey with increased detail and clarity.

ADVICE

Looking back, EMD Serono is proud of the progress made, particularly given that very few biopharmaceutical organizations have undertaken DE&I measurement with such vigor and dedication. When it comes to lessons learned, the implementation leads at EMD Serono recommend ensuring clarity around the definition of each measure that will be rated in the model. For example, description or definition of each domain may be perceived differently by different stakeholders; without clear alignment on understanding, it's difficult to standardize results. An investment in clarity on the front end of developing your model will save time later down the road, and it will also make the model more actionable for teams.

"Implementing the DE&I Maturity Model at EMD Serono required a balance of clear expectation-setting of what we need to score, but also flexibility in how that scoring will take place," said EMD Serono's Head of In Country Clinical Operations Americas. "We ultimately found that by giving our teams a clear tool, along with some flexibility in how they will come together to score each domain, we can create an integrated DE&I measurement process that not only works within our organization, but also brings better outcomes to the patients we serve."

ORGANIZATION

EMD Serono

CONTACT

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ORGANIZATION TYPE

Industry

IMPLEMENTATION DATE

2023

TOPIC

Diversity

RELATED CTTI PROJECT

[Diversity in Clinical Trials](#)

CTTI RESOURCES

[CTTI Recommendations: Increasing Diversity in Clinical Trials](#)

[Diversity Maturity Model for Organizational-Level Strategies](#)