

CASE STUDY HIGHLIGHTS:

Achieving and Exceeding Clinical Trial Participant Diversity Targets

Using Customized Tools, Applications, and a Dynamic Enrollment Tracker

BACKGROUND

Hepatitis C Virus (HCV) infection is a potentially curable chronic liver infection that can cause cirrhosis, liver cancer, and even death. HCV affects approximately 170 million individuals worldwide and disproportionately impacts Black and Latinx individuals. Compared to other racial subgroups, Blacks demonstrate lower responses to some HCV treatments (e.g., interferon-alpha). Also, major HCV genotypes vary in prevalence (based on regional and ethnic/racial demographics), severity, and treatment response.



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Considering the disparities in the burden of HCV and response to treatment, as well as the variance in genotypes, Merck set an enrollment goal of 20% people of color in its pivotal phase 3 “C-EDGE” program evaluating the combination of two products in treating HCV, elbasvir/grazoprevir (Zepatier®).

APPROACH

To achieve diversity in its clinical trials, Merck utilized its ‘Diversity in U.S. Clinical Trials Core Team’ to create sustainable solutions for appropriate site selection, customized tools and applications, and a dynamic participant enrollment tracker.

SITE SELECTION

The program used targeted site selection and selected to work only with centers and sites that were confident and able to provide evidence in their ability to meet the recruitment goals in the aggressive timelines set.



**MULTI-REGIONAL
CLINICAL TRIALS**

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

CUSTOMIZED RESOURCES AND MATERIALS

The program partnered with The Center for Information and Study on Clinical Research Participation (CISCRP) to develop customized tools and patient education materials for racially and ethnically diverse participants. These resources included tools for sites to use such as:

- cultural pointers for healthcare professionals
- implementation guides for sites
- bi-lingual consumer materials and brochures that emphasized how patients had been part of the healthcare team designing the trial and not just as recipients of healthcare treatment.

The tools highlighted the values of clinical research, the rights of patients and participants in research, and what the participants could expect.

COMMUNICATION STRATEGY

The program developed a communication strategy focused on community building and site engagement using the DrugDev Spark platform. This offered a central cloud-based platform to allow all study staff to access materials securely and efficiently.

The screenshot shows the DrugDev Spark platform interface. At the top is a dark blue header with the 'd DrugDevSpark' logo on the left and a user profile icon on the right. Below the header, a welcome message reads: 'Welcome to DrugDev Spark™, the most comprehensive unified clinical solutions suite. Please select a solution below to learn more or to sign in to your account.' The main content area is organized into three columns under the heading 'Trial Conduct'. The first column, 'Planning', includes 'Site Selection', 'Site Feasibility', and 'Patient Feasibility'. The second column, 'Startup', includes 'Site Activation', 'eConsent', and 'Learning Management'. The third column, 'Trial Conduct', includes 'Payments', 'Site Engagement', 'Document Exchange', 'Safety Letters', 'Patient Engagement', and 'eTrackers'. Each item is represented by an icon and text. At the bottom right, the URL 'http://drugdevspark.com/' is displayed.

d DrugDevSpark™

Welcome to DrugDev Spark™, the most comprehensive unified clinical solutions suite. Please select a solution below to learn more or to sign in to your account.

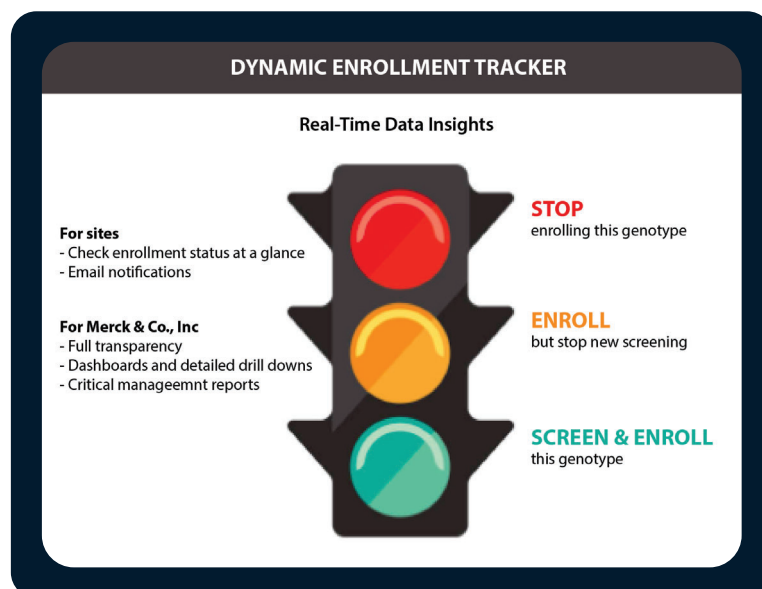
Planning	Startup	Trial Conduct	
Site Selection	Site Activation	Payments	Safety Letters
Site Feasibility	eConsent	Site Engagement	Patient Engagement
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<http://drugdevspark.com/>

It featured dashboards, enrollment updates, educational videos, team photos, electronic newsletters, and operational spotlights. These tools helped sites trust and rely on the content and the extended network.

DYNAMIC ENROLLMENT TRACKER

The dynamic enrollment tracker provided real-time data feedback by leveraging the integrated DrugDev Spark platform system. The tracker was used in tandem with targeted email blasts and an automatic document notification system that deployed a “stop-light” method. This transparent and identifiable visual imagery allowed study leads to check enrollment status and critical management reports quickly.



The enrollment tracker was designed and configured to meet specific study needs, including a secure repository of all the study documents with a uniform folder structure that was applied to all studies in the program.

RESULTS

The C-EDGE program exceeded the diverse enrollment goals of 20%. The actual number screened was 26.6% and the randomized diverse population was 26.5%.

CONCLUSION

Merck demonstrated that enrollment of diverse population can be improved and targets exceeded through the use of customized tools and applications, and by utilizing a dynamic participant enrollment tracker. Additionally, creating a plan at the start with clear diversity goals was key.

Although there were significant program challenges (short enrollment period, competitive landscape, aggressive timelines, managing enrollment on a global basis, and requirement for reliable, real-time reporting and site communication), the enrollment of people of color not only met but exceeded the goal.

For citations and more information on this case, please see the **MRCT Center toolkit**.