



Diversity Case Studies

Cardiovascular Diversity Enrollment Case Study

Overview

- Medical device study evaluating the use of a technology platform (smartphone app) to evaluate heart rate through fingertips
- Study protocol required that 30% of the total enrollment (85) be subjects with a skin type of Fitzpatrick V or VI (brown and black skin tones)

Problem

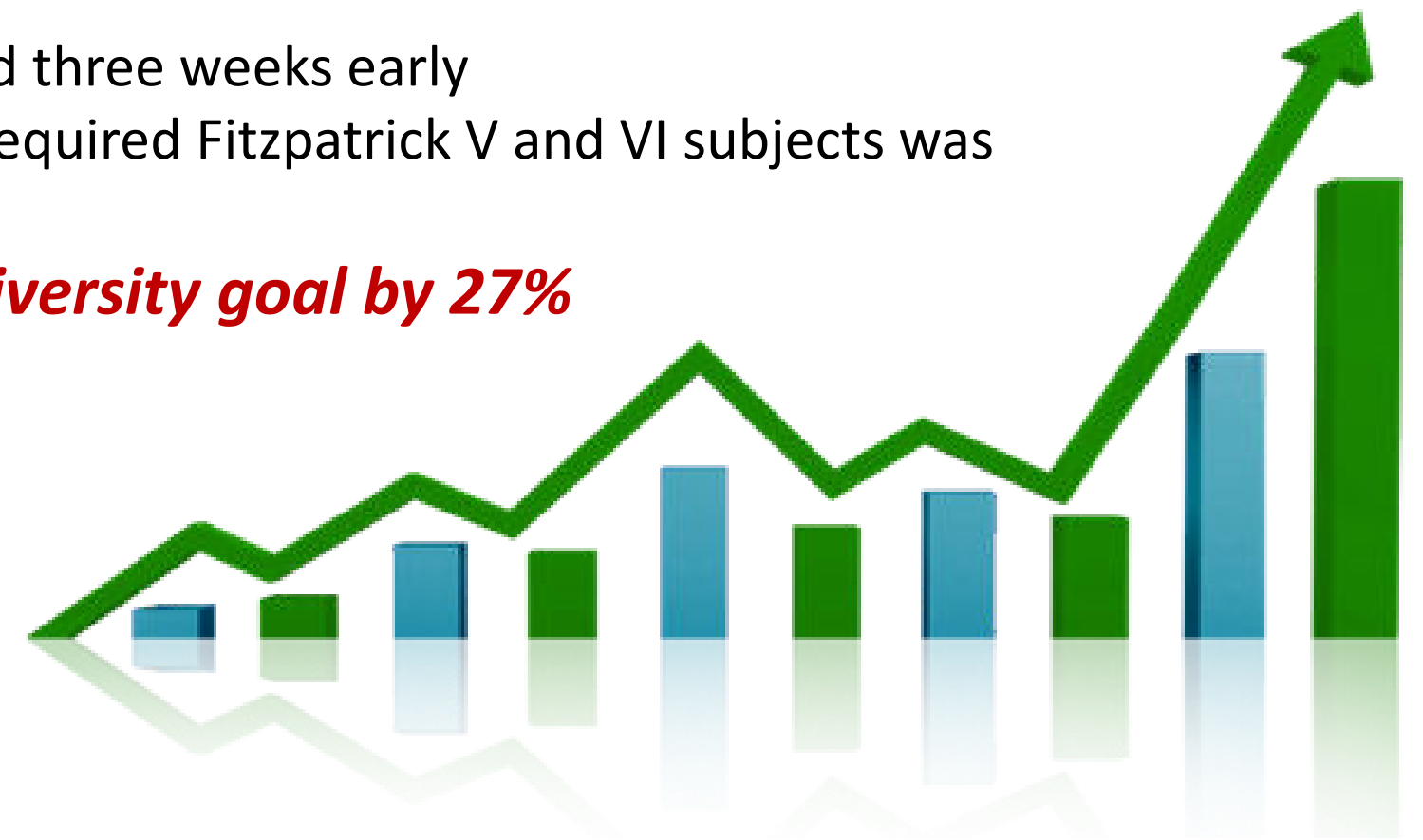
- Accurate fingertip readings can be more challenging with subjects of a darker skin tone

Solution

- TOTAL identified seven sites that had immediate access to subjects who would meet the Fitzpatrick V and VI skin types
- Enrollment was stratified where the Fitzpatrick V and VI subjects were enrolled first and then the remainder of enrollment for all other skin types was opened to finish complete enrollment

Results

- Study enrolled three weeks early
- 33 of the 26 required Fitzpatrick V and VI subjects was enrolled
- ***Exceeded diversity goal by 27%***



Aesthetic Diversity Enrollment Case Study

Overview

- Aesthetic study evaluating the safety and efficacy of a filler for the infraorbital hollow
- 152 total subjects were required to be enrolled
- Study protocol required that 10% of total enrollment be Fitzpatrick IV, V, or VI
- Known interim analysis by the FDA halfway through enrollment

Problem

- After interim analysis conducted by the FDA, the FDA made the following enrollment recommendations: 20% of total enrollment should be Fitzpatrick IV, V, or VI; 14% of total enrollment should be Hispanic; 10% of total enrollment should be Black; and 6% of total enrollment should be Asian
- TOTAL did not select the sites to participate in this study

Solution

- TOTAL conducted an enrollment analysis among all sites to determine immediate, direct access to the upper Fitzpatrick skin types and the other races/ethnicities identified by the FDA
- Enrollment was stratified where the Fitzpatrick IV, V and VI subjects were enrolled first and then the remainder of enrollment for all other skin types was opened to finish complete enrollment
- TOTAL worked with sites individually on broadening the site's community engagement efforts and placed recruitment ads on several social media platforms (i.e., Facebook, X, and Instagram)

Results

- Total enrollment of 152 subjects was completed on time
- 24% of total enrollment was classified as Fitzpatrick IV, V or VI (20% over goal)
- ***Diversity goal achieved was 80%; results were favorable by the client given the limited time to achieve these goals***

Aesthetic Diversity Enrollment Case Study

152 participants in US

Protocol requires **10%** of participants= Fitzpatrick skin type (FST) IV, V or VI

FDA added strong recommendation of racial/ethnic diversity goals: FST IV-VI **20%**, Hispanic **14%**, African American **10%**; Asian **6%**
(Protocol not amended)

Enrollment of 152 subjects by 3/31/22.
Enrolled FST IV-VI= **24%**, Hispanic= **15.7%**, African American= **4.6%**, Asian= **3.9%**



Key Point
of Contact



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