

CSL's Commitment to Including a Representative Patient Population in the **CSL300_2301 Clinical Study**

At CSL, we always want to improve our understanding of how well our therapies work for the people who need them. Sometimes there are differences in the way that therapies perform based on someone's age, sex, race or ethnicity. CSL actively asks questions to understand those differences and works hard to study where they exist. This helps us to ensure all these different groups are represented in our trials.

Historic barriers to participation in trials exist that may be greater for some groups. Therefore, we will make special efforts to make clinical trials understandable and accessible to all groups.

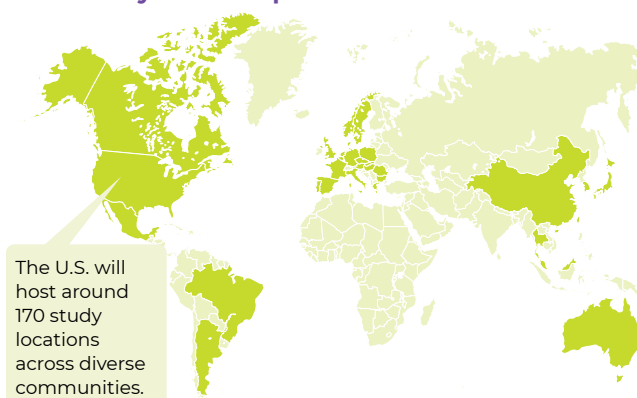
CSL300_2301 is a great example of where we are making special efforts to recruit populations impacted by end-stage kidney disease (ESKD). This document is a summary of our plan to ensure that the people in Part 2 of the 2-part CSL300_2301 study come from diverse backgrounds, just like those living with ESKD. Including enough representatives from all of the groups of ESKD patients will help us find a treatment that works for anyone who needs it.

In this summary, you will find:

- ✓ An **overview** of Part 2 of the CSL300_2301 study
- ✓ The **enrollment goals**, which are the numbers of participants CSL hopes to include in this study by **age, sex, race and ethnicity**
- ✓ The **steps CSL is taking** to make this study accessible and inclusive to a diverse group of people



The study will take place in over 30 countries



What is ESKD?

In **end-stage kidney disease (ESKD)**, a person's kidneys can no longer properly remove waste and other substances from the body. Diabetes is one of the most common causes of ESKD, along with other conditions that affect kidney function. ESKD can lead to increased inflammation and other health problems, such as heart disease. People with ESKD typically need dialysis, which is a treatment that removes extra waste and fluid from the blood. In some cases, a kidney transplant may be needed.

What is the CSL300_2301 study?

In the CSL300_2301 study, researchers want to learn more about how safe the drug CSL300 is and how well it works in people with ESKD on dialysis who also have heart disease or diabetes.

The drug **CSL300**, also known as **clazakizumab**, is designed to protect the heart and blood vessels by reducing **inflammation** in people with ESKD. Researchers hope that using CSL300 along with dialysis could help reduce the risk of heart attacks or heart-related deaths in people living with ESKD.

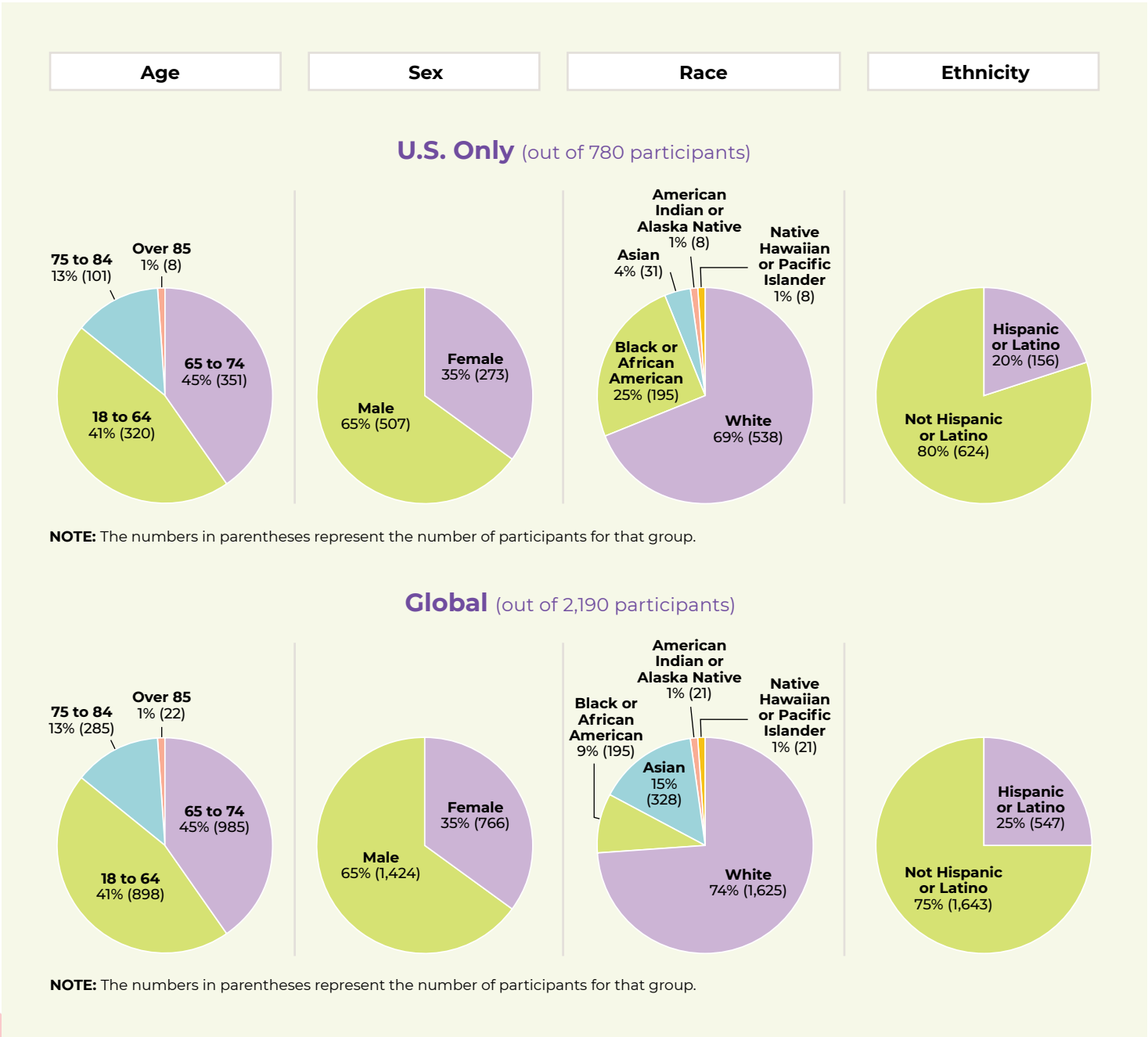
What are the enrollment goals for the CSL300_2301 study?

Part 2 of the study will include about 2,190 participants. About 780 of these participants will be from the United States. CSL's goal is that the study participants are as diverse as the patients living with ESKD in the U.S. and globally. The enrollment goals are divided by age, sex, race and ethnicity. The term race refers to a type of categorization based on physical traits. Ethnicity refers to cultural background and might include things like history, language or nationality.

Some of the enrollment goals for the U.S. are that:

- About 45% of participants are 65 to 74 years old
- About 35% of participants are female
- About 25% of participants are Black or African American
- About 20% of participants are Hispanic or Latino

The pie charts below show the enrollment goals for participants in the U.S. and for participants globally.



How were the enrollment goals chosen?

To set the enrollment goals for this study, CSL considered different data that represents the likelihood of different groups of people developing ESKD. The data also considered the total population size of these groups in the U.S. and globally:



The 2023 U.S. census data

The census data gave an updated breakdown of the U.S. population and its diversity. Global goals were then based on the U.S. population data to help meet the overall enrollment goals.



Results from Part 1 of the CSL300_2301 study

The first part of the study successfully included participants from diverse backgrounds and showed that CSL300 worked similarly in all participants, no matter their age, sex, and racial or ethnic differences.



The rates of ESKD in the U.S. population

The data from the 2023 United States Renal Data System (USRDS) showed which groups are most likely to develop ESKD and was a critical part in setting the enrollment goals. For example:

- Older adults are more likely than younger adults to have heart disease, diabetes and ESKD.
- Men have a higher risk of ESKD than women.
- Certain racial and ethnic groups are at higher risk for ESKD. Black people are 4 times more likely than White people to develop ESKD.

The plan of action

To reach these enrollment goals, CSL made a list of strategies:

- **Staying organized:** CSL will hold regular meetings to monitor enrollment progress and make sure that enrolled participants understand the importance of attending their appointments consistently. Throughout the study, CSL will track performance to meet diversity goals and adjust strategies as needed to support representative enrollment.
- **Partnering with patients:** In 2022, CSL met with ESKD patients who were on dialysis to give their feedback on this study. This feedback informed the timing of study procedures and helped improve informed consent forms and questionnaires. It also guided the development of educational materials, such as brochures and videos, to help potential participants learn about the importance of clinical studies and the increased risk of inflammation and other health problems in dialysis patients.
- **Making study sites more accessible:** Study sites will be chosen in a variety of areas, including cities, suburbs and rural communities, to make them more accessible for people of diverse backgrounds to participate. Clinical research educators will work with these sites to reach out to and educate diverse patients on the risks and potential benefits of participation.
- **Working with nonprofits:** CSL will partner with nonprofits, like the National Kidney Foundation, to improve awareness of kidney care.

CSL created this summary with the help of people living with ESKD and with CISCPR, an independent nonprofit organization. CSL is sharing this plan to include a representative patient population with the public.

If you have questions about this summary, please contact CSL at clinicaltrials@cslbehring.com.

If you want to learn more about this study, please visit csltrials.com/participate/detail?trialid=NCT05485961.



CSL is a global biopharmaceutical company committed to improving the lives of people living with ESKD. CSL offers biotherapies for other rare and serious diseases, including bleeding disorders, immunodeficiencies, hereditary angioedema and neurological disorders. To learn more about CSL and its studies, please visit csl.com and csltrials.com.

CSL is headquartered in Melbourne, Australia.