

Request for Information- Patients Consented:

“I note in Table 6.1.10.1.3-2 , in the first line, under number of patients consented, the entry is 201. Is this correct? I know that there were 189 patients screened.”

Vericel Response

A total of 189 patients underwent 201 screening procedures. A total of 12 patients were screened twice. Per protocol, sites were allowed one opportunity to re-screen each patient who fails to meet eligibility criteria at the Screening visit or index arthroscopy (MACI00206 protocol Section 7.3). See summary table below.

All Patients Screened (based on assigned patient number) ¹	Number of Patients Screened	Number of Patients Screened Twice
201	189	12

Source: MACI00206 CSR Listing 16.1.2.1 (in this listing, a total of 12 patients are listed twice; a superscript of 1 indicates the patient identifier assigned at the first screening and superscript 2 indicates the patient identifier assigned at the second screening)

¹ Patients who were screened twice were assigned two different patient numbers. The patient number for a patient at rescreening will have a “9” as the third digit instead of the default “0” used for initial screenings.

Please see attached : LISTING 16.1.2.1, Demographics: ALL PATIENTS SCREENED included in the BLA.