

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.

<b>All Patients Screened (based on assigned patient number) <sup>1</sup></b>	<b>Number of Patients Screened</b>	<b>Number of Patients Screened Twice</b>
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)

<sup>1</sup> 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.