

ALMIRALL, S.A.

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Clinical Trial Protocol Title:

A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, CONTROLLED STUDY, TO ASSESS THE EFFICACY AND SAFETY OF P-3074 CUTANEOUS SPRAY SOLUTION, IN THE TREATMENT OF MALE PATTERN BALDNESS.

Statistical Analysis Plan Amendment Number: 1
Statistical Analysis Plan for Clinical Trial PM1541

Prepared and Approved by:

Almirall PPD
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3. Section 8 of the SAP (Changes in Planned Analyses)

Old text:

Section 8. Canges in planned analyses
Not applicable

New text:

Section 8. Canges in planned analyses

For a better understanding of the ITT population definition, the following wording has been modified:

- 1- Protocol definition (see section 10.1.1):
ITT population: all patients who will have measurements both at baseline and on treatment

- 2- SAP definition (see section 5.3):
ITT population: all patients who will have measurements both at baseline and on treatment: i.e. patients who have measurements in regards to hair count both at baseline and on treatment.

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