## CLINICAL STUDIES OF PLENVU®

During its development, PLENVU<sup>®</sup> was called NER1006. After some small studies indicated that it was safe, and that it would work well as a bowel cleanser, Norgine conducted three large studies, involving nearly 2000 people, to prove this.

All three studies started in the year 2014, and so the studies were called NER1006-01/2014, NER1006-02/2014, and NER1006-03/2014, to show that they were the first, second and third studies of the compound in that year. Endings were then added to the study names, to tell the reader something about the study itself.

Study NER1006-01/2014 compared NER1006 (PLENVU<sup>®</sup>) with another bowel cleanser called trisulfate solution. In this study, NER1006 or trisulfate solution was given as one dose during the evening before colonoscopy and one dose on the morning of the colonoscopy. The name of the study therefore had "NOCT" added to it, which is short for "nocturnal" (as the doses were taken in the evening and morning, with a rest overnight). A link to the summary of this study can be found here: NER1006-01/2014 (NOCT).

Study NER1006-02/2014 compared NER1006 (PLENVU<sup>®</sup>) with MOVIPREP<sup>®</sup>, which is another bowel cleanser made by Norgine. This study was to test whether our new bowel preparation cleans the bowel as well as MOVIPREP<sup>®</sup>, when given in the same way – one dose in the evening and another on the morning of the colonoscopy. It also tested whether it works when both of the doses of NER1006 are given on the morning of the colonoscopy. The study name had "MORA" added to it, because this group of patients took NER1006 in the morning only. A link to the summary of this study can be found here: <u>NER1006-02/2014</u> (MORA).

The third study, study NER1006-03/2014 compared NER1006 (PLENVU<sup>®</sup>) with another bowel cleanser, sodium picosulfate and magnesium salt, when the bowel cleansers were taken the day before colonoscopy. Again to show the way the products were given, "DAYB" (short for "day before") was added to the end of the study name. A link to the summary of this study can be found here: <u>NER1006-03/2014 (DAYB)</u>.