

## Independent audit finds UCB highly compliant per FDAAA 801 and FDAAA 801 Final Rule

The audit confirms that UCB has registered and posted results for all trials required under the regulations. The results are confirmed in a 2018 [STAT News](#) analysis.

In November 2017, an independent third-party audit of UCB's registry and results reporting compliance on ClinicalTrials.gov found that UCB was highly compliant.

UCB was 100% compliant with on-time registration as of a cut-off date of 19 October 2017.

UCB was 100% compliant with results disclosure and 94% compliant with on-time results disclosure as of the cut-off date of 19 October 2017.

All the late results postings occurred in 2009 and were for clinical trials of approved products. Each was posted within two months of the due date with one exception being posted within eight months of the due date. See the table below.

### Trials Posted Late on ClinicalTrials.gov

| Study Number | NCT ID      | Brief Title / Description   | Product            | Approval Date | Results Due | Results First Received |
|--------------|-------------|---|--------------------|---------------|-------------|------------------------|
| N01148       | NCT00152516 | Long-Term, Follow-Up Study of the Safety and Efficacy of Levetiracetam In Children with Partial Onset Seizures          | Levetiracetam      | 2008-Apr-22   | 2009-Jun-30 | 2009-Aug-27            |
| SP0745       | NCT00235443 | A Follow-On Trial to Assess the Long-Term Safety and Efficacy of SPM 927 in Painful Distal Diabetic Neuropathy          | Lacosamide         | 1999-Nov-30   | 2009-Jul-31 | 2009-Aug-31            |
| C87042       | NCT00308581 | Certolizumab in Crohn's Disease Patients with Loss of Response or Intolerance to Infliximab                             | Certolizumab Pegol | 2008-Oct-28   | 2009-Apr-30 | 2009-Jul-07            |
| SP0887       | NCT00401830 | Assessing Efficacy and Safety of Lacosamide Compared to Placebo in Reducing Signs and Symptoms of Fibromyalgia Syndrome | Lacosamide         | 2008-Oct-28   | 2009-Feb-28 | 2009-Sep-22            |
| SP0906       | NCT00440518 | A Study Designed to Test the Effectiveness and Safety of Treating Patients with Lacosamide for Migraine Prophylaxis     | Lacosamide         | 2008-Oct-28   | 2009-Jul-31 | 2009-Aug-03            |

The audit also found one trial which suggested missing results based upon public information. This trial was part of a development program that was globally discontinued and therefore not required to have results disclosed. In full transparency, UCB voluntarily shared the results of this trial in July 2018 to avoid any misinterpretation. See the table below.

### Terminated Trials with Results Missing on ClinicalTrials.gov

| Study Number | NCT ID      | Brief Title / Description   | Product     | Primary Study Completion Date | Results Due | Results First Received               |
|--------------|-------------|---|-------------|-------------------------------|-------------|--------------------------------------|
| SL0012       | NCT01408576 | Open-Label Extension Study of Epratuzumab in Subjects with Systemic Lupus Erythematosus | Epratuzumab | 2016-Feb-01                   | 2017-Feb-28 | No Results Posted as of October 2017 |

UCB will consider conducting additional external audits whenever there are substantial updates to the registration and results reporting requirements of either Clinical Trials.gov or the EU Clinical Trials Register. These external audits are in addition to any internal assessments that are performed on a more regular basis to ensure ongoing compliance.