

UCB Position Statement

UCB is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases in immunology and neurology.

To that end, UCB supports responsible sharing of clinical study data as a way to uncover new scientific knowledge or insights and thus ultimately benefit our patients and our other stakeholders

In alignment with the 5 guiding principles established by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) for the responsible sharing of clinical study data, UCB commits to the following:

Enhancing Data Sharing with Researchers

UCB pledges to share, upon request from qualified researchers, anonymized patient-level and study documents redacted for personally identifiable information, from Phase 2-4 interventional clinical studies in patients for approved medicines and indications, as necessary for conducting legitimate research. Each request will be evaluated based on criteria that balance the need to advance science with the need to protect patient privacy. For further details, see <https://clinicalstudydatarequest.com/>.

Enhancing Public Access to Clinical Study Information

Following approval of a new medicine or new indication for an approved medicine in the US and EU (the Food and Drug Administration (FDA), European Medicines Agency (EMA), or national competent authorities of EU Member States), UCB pledges to make available the synopses of Clinical Study Reports (CSRs) for clinical studies in patients submitted to these regulatory authorities on or after January 1, 2014. The synopses of CSRs will be redacted to protect personally-identifiable information and company confidential information.

Sharing Results with Patients Who Participate in Clinical Studies

UCB has pioneered the creation of lay summaries and regularly posts these to our website to better inform study participants, patients and the public of UCB-sponsored clinical studies. UCB will also work with regulators to establish additional mechanisms for providing factual summaries of clinical study results and make these summaries available to study participants in a language appropriate for the purpose.

Certifying Procedures for Sharing Clinical Study Information

UCB certifies that it will set up all policies and procedures to implement the data sharing commitments as established with EFPIA/PhRMA.

Reaffirming Commitments to Publish Clinical Study Results

UCB reconfirms its pledge to attempt to publish all company-sponsored clinical studies in the scientific literature, regardless of the outcome, and will continue to submit the results from all clinical studies. UCB adheres to established guidelines in medical and scientific publishing including, but not limited to, International Committee of Medical Journal Editors (<http://www.icmje.org/>) and Good Publication Practice (<https://goo.gl/oJrk4q>).

For any questions about our Data Sharing policy, please contact: DataSharing.Coordinator@ucb.com.