

BioNTech Transparency Declaration

The sharing of health information is fundamental for the good functioning of healthcare services, for patients' safety, and to advance research and improve public health.

BioNTech is committed to disclosing health information, in line with all applicable laws and regulations, including data privacy laws.

In addition, BioNTech commits to the below items for all interventional clinical studies (Phase I and beyond) sponsored by BioNTech that are investigating authorized treatments, non-authorized use of authorized treatments, and investigational treatments (i.e., non-authorized treatments).

This commitment only applies for clinical studies:

- With first study participant in (FPI) after the date of issue of this declaration.
- Where BioNTech is not prohibited from disclosing the health information, for example by contractual agreements with development partners.

Our commitments:

- 1) Irrespective of where the study is performed, to register all studies on the website clinicaltrials.gov before enrollment of the first study participant (i.e., FPI).
- 2) Irrespective of where the study is performed, to publicly post the outcomes for all primary and secondary outcome measures, irrespective of outcome, on the website clinicaltrials.gov within 12 months of study completion (i.e., last participant last visit, "LPLV").
- 3) To publicly post expert summaries of the outcomes for all primary and secondary outcome measures, irrespective of outcome, on a publicly-accessible website within 12 months of LPLV. Any personal data or commercially confidential information in these summaries will be redacted.
- 4) To post lay summaries of key results on a publicly-accessible website within 12 months of LPLV.
- 5) To submit the outcomes for all primary and secondary outcome measures, irrespective of outcome, for publication in academic journals within 30 months of LPLV.
- 6) To share upon request clinical study reports (ICH E3) that were submitted to health authorities in support of granted applications for marketing authorization in the European Union and/or United States:
 - This sharing will be subject to contractual control to highlight that no personal data will be shared and to prevent commercial use of the shared information.
 - All personal data and commercially confidential information in shared clinical study reports will be redacted.
 - This sharing will be no earlier than 12 months after LPLV.
- 7) To publicly post reports of compliance with this declaration once per year (these reports will summarize the number of requests for sharing, the outcomes of the requests, and the outcomes of any audits performed on compliance with this declaration).

ICH E3: ICH E3 Structure and content of clinical study reports, see [here](#).

Compliance with this declaration

The requirements of this declaration are set out in written standard operating procedures. Compliance with these requirements will be subject to regular audits.