BIONTECH

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 (at the time of study start) 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:

- Where the first trial participant has given informed consent on or after 25 March 2022.
- Where BioNTech is not prohibited from disclosing health information, for example by contractual agreements with development partners.

Our commitments:

1) Irrespective of where the trial is performed, to register all studies on the website clinicaltrials.gov before the first trial participant has given informed consent.
2) Irrespective of where the trial is performed, to publicly post results for all primary and secondary outcome measures, irrespective of outcome, on the website clinicaltrials.gov within 12 months of trial completion (i.e., last participant last visit [LPLV]).
3) To publicly post an ICH E3-based clinical trial report synopsis, irrespective of outcome, on the BioNTech Clinical Trials website (https://clinicaltrials.biontech.com/) within 12 months of LPLV. Any personal data or commercially confidential information in these synopses will be redacted.
4) To post lay summaries of key results on the BioNTech Clinical Trials website within 12 months of LPLV.
5) For Phase 2 to 4 clinical studies, to submit results 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 trial 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:
    - All personal data and commercially confidential information in shared clinical trial reports will be redacted.
    - This sharing will be no earlier than 12 months after LPLV.
7) To share upon request anonymized data from interventional clinical studies conducted by BioNTech with the COVID-19 vaccine COMIRNATY® (and variant vaccines) that were submitted to health authorities in support of applications for marketing authorization in the European Union and/or United States.
    - Requests from appropriately qualified researchers must be submitted to the relevant data sharing platform for assessment.
    - Data will be available beginning 24 months after LPLV.
8) 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.