

statement

IFPM A Response on Joint Statement on transparency and data integrity by International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO)

Geneva, 7 May 2021 – The R&D-based biopharmaceutical industry is fully committed to enhancing public health through responsible sharing of clinical trial data in a manner that ensures safeguarding the privacy of patients, clinical investigators and trial participants; respecting the integrity of national regulatory systems; and maintaining incentives for investment in biomedical research.

We recognize the call from ICMRA & WHO to share knowledge and information with the scientific community to better inform patients, healthcare providers and researchers and the public about ongoing regulatory processes and procedures to facilitate trust in our shared interest in providing safe and efficacious treatments and vaccines. We are widely supportive of sharing data and providing access to clinical trial results.

The R&D-based industry provides access to trial results data for the benefit of public health. For example, biopharmaceutical companies routinely collaborate with academic researchers, publish their clinical research in peer-reviewed literature, and share clinical trial information including results on public websites (such as WHO International Clinical Trials Registry Platform, US NIH ClinicalTrials.gov database, Health Canada Clinical Information Portal, EU Clinical Trials Register, EMA's Clinical Data Website and Japan Registry of Clinical Trials). In addition to enhance patient understanding about the clinical trials in which they have participated, biopharmaceutical companies are collaborating with national regulatory authorities to adopt mechanisms for providing lay summaries of clinical trial results to research participants consistent with applicable laws and rules.

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