

October 4, 2023

## Policy of the Japan SMO Association (JASMO) on Ensuring the Integrity of Clinical Trial Data

Dear Esteemed Stakeholders,

We wish to emphasize our unwavering commitment and the proactive measures taken by our association to ensure the integrity of clinical trial data.

Our association has consistently championed the cause of data integrity. Recognizing the critical importance of a robust framework, we pioneered the "SMO Guidelines for Ensuring the Integrity of Clinical Trial Data" on June 5, 2015. This was not just a declaration; we actively ensured its widespread adoption among our member companies. Building on this foundation, on June 24, 2016, we introduced the Japan SMO Association Audit Regulations (hereinafter referred to as the "J-Audit Regulations"). This was a decisive step, leading to comprehensive audits across all our member companies. And our journey didn't stop there. On March 20 of this year, we refined the J-Audit Regulations, reinforcing our commitment. This revision ensures that our member companies not only provide essential support to clinical trial sites in line with the Guidelines but also adhere strictly to the ICH-GCP, regulations, and global standards.

Furthermore, our association, in collaboration with the Japan Pharmaceutical Manufacturers Association Drug Evaluation Committee and the Japan CRO Association, has taken a united stand. We have crafted the "Data Integrity Declaration - Our Pledge" to underscore the paramount importance of data integrity. We believe that every individual involved in clinical trials and studies should not only recognize but also champion this cause. Our dedication to this mission is evident in our relentless efforts to promote this declaration. A testament to this commitment was our recent joint seminar at the 23<sup>rd</sup> Conference on CRC and Clinical Trials 2023 in Okayama. Here, we expanded the reach of the Data Integrity Declaration, rallying the entire industry towards a shared vision of unwavering data integrity.

Our member companies embody this commitment. Not only do they adhere strictly to the Guidelines, but they also engage in rigorous self-assessments aligned with the J-Audit Regulations. Every day, we strive to ensure that the essence of the "Data Integrity Declaration - Our Pledge" permeates every facet of our operations.

To all our stakeholders, we humbly seek your understanding and support for our unwavering dedication. We earnestly hope that you will continue to bestow your trust upon our association and its esteemed member companies.

With the utmost respect and gratitude,

October 4, 2023

Miho Goto/President of Japan SMO Association