

Subject: Reasons for re-consultation D8.3

Dear Stakeholders,

In the Xt-EHR Joint Action, we place great importance on ensuring that all deliverables meet high standards of quality, relevance and consistency. As part of our commitment to stakeholder engagement, we are initiating a second consultation round for the draft deliverable D8.3 *“Wellness application labelling guideline”*.

The deliverable was initially shared as an early draft version, with major sections not yet fully developed. D8.3 is intended to propose guidelines for wellness applications in Europe, aligned with existing EU regulations. However, at the time of the first stakeholder consultation, these guidelines were still under development. Consequently, the most critical part of the deliverable—its practical recommendations for stakeholders and the market—was not available for review.

To ensure that your feedback is both meaningful and impactful, and that the final deliverable reflects the latest regulatory context and stakeholder needs, we are now sharing an updated version of D8.3 for a second round of consultation.

We deeply value the insights and expertise of stakeholders across all EU Member States. Your contributions are essential to ensuring that the document not only meets formal requirements but also reflects the diverse perspectives and practical realities of those working in the field. This collaborative approach supports the development of the future European Health Data Space regulation and contributes to improving healthcare delivery and access to health data for citizens across Europe.

We kindly invite you to review the revised draft and share your feedback during the consultation period, which will run from 5th November to 5th December.

Thank you for your continued support and valuable contributions to the Xt-EHR Joint Action.

Christos Schizas

Coordinator of Xt-EHR project