

Comments	Proposed change	Observations of the team
#1 The aspect of overall authority and related standards issues of trans-border health complaints, investigations, audit and evidence gathering and preservation, and sanctions regimes are not addressed. (Perhaps another dimension for both 'Figure 3 — Landscape affecting the IPS Guide for European Use' and 'Figure 4 Table 2 — Examples of stakeholder involvement in Information Governance'. I suspect these aspects could usefully be covered elsewhere through other documentation but their omission at this stage may require an explicit comment).		Thank you. This is for further consideration and inclusion in the next revision.
#2 Probably goes without saying but an annexed informative worked example would probably aid reader understanding of where and how to apply the guidance in practice - perhaps another part to the document?	annexed informative worked example showing not just the exchange format, but also what a conformance statement might look like.	This is for further consideration and the next iteration after more implementation experience of the IPS is available.
#3 A documentation/standards map checklist might be developed as an annex. This would also help to ensure comprehensive application of the guidance allowing stakeholder plug-ins of local / national policies, procedures and requirements etc where applicable. (For IPS trust and confidence purposes, I'm thinking here of both consistency of application and the ability to evidence attainment (not just GDPR compliance)).	documentation/standards map checklist be developed as an annex	This too, is worthy of development and inclusion in the next version of the guideline.
#4	The technical assessment is well described but I suggest to refine the current content to better address the quality assessment / evaluation of the IPS in their different aspects. quality of data; fitness for purpose; and so on...	This guideline will be revisited as the use of the IPS matures. Issues of quality go beyond the output of the document, and the value and quality comes from considering its outcomes. This will be considered for the next iteration.