eCTD 4.0 Pilot Checklist

eNNOV
Software for Life

☐ DECIDE WHETHER TO PARTICIPATE

○ **Get the key pilot details**

Confirm the dates and regional specification with the Health Authority.

Identify whether this is a technical pilot, in which the submission will not be assessed, or a live pilot, where a real submission using real data is assessed by the Health Authority. Live data and submissions are a major risk factor: consider whether the benefits of participating in the pilot outweigh the risks if the pilot submission isn't successful.

○ **Talk to your submission tool vendor**

Close collaboration with your submission tool vendor will be essential for success. Let your vendor know that you're interested in participating in the pilot, sharing all available information.

○ **Assess your resources**

Forecast planned submissions during the pilot period. Participating in the pilot will take resources: is there a risk that your publishing team won't be available to support critical deadlines?

○ **Get stakeholder approval**

Consider the risks and benefits of pilot participation, the resources that will be required and how your submission tool vendor can support you.

☐ PREPARE FOR PARTICIPATION

○ **Confirm your participation with the Health Authority and your vendor**

Once the Health Authority has approved your participation in the pilot you must inform your submission tool vendor.

○ **Organise training for your publishing team**

Publishers must receive some training on how to submit eCTD 4.0 submissions. This standard is quite different to eCTD 3.2 and training sessions with your vendor are highly encouraged.

Review the regional specification to be used in the pilot. Your publishing team should use the specification to familiarise themselves with the new format and any best practices included by the Health Authority.

○ **Plan your pilot submissions**

Work with your vendor to plan when you will make your pilot submissions. Vendors will need the final specifications with enough time to prepare and test the pilot tool, and your team will need time to train on the new tool.

○ **Evaluate the vendor solution**

Once the vendor has prepared the tool for the pilot, your publishing team will need to complete training and ensure that they are prepared to make submissions during the pilot. eCTD 4.0 is a new standard: ensure that the tool supplied by your vendor offers feature parity with eCTD 3.2.

If live data is to be used in the pilot, ensure the vendor solution is fully validated. This is likely to require additional time for the vendor to validate the tool, but it is essential for any live submission.

☐ DURING AND AFTER THE PILOT

○ **Make your submission**

The publishing and acceptance of the submission is the penultimate step in the pilot. Ensure that your publishing team has support—internal and from your vendor—during the publishing and submission step.

○ **Review the pilot experience**

Once the pilot is complete, an assessment should be conducted on all steps in the process. This can be done in conjunction with the Health Authority and the submission tool vendor, providing feedback on potential issues or areas for improvement.