

Projects Needing FHIR R5

this is a summary - there detailed submissions are [here](#).

1) FDA: Pharmaceutical Quality/Chemistry, Manufacturing & Controls (PQ/CMC)

This project is dependent on at least 6 resources that are effectively new in R5. The project was established on the basis that V3 was inadequate and R5 would be available in Q3 2020. Delays beyond this point have a direct impact on the planned timeline. An STU update making these revised resources available would be sufficient for progress to be made.

2) Health Canada: Electronic Licencing & Inspection System (ELIS)

While a different project and a different regulator ELIS is using the same set of resources as PQ/CMC and has the same timescale expectations.

3) EMA: IDMP

The same set of resources again, but this time for the implementation of the IDMP standard which is mandated by European law and which the EMA are implementing using FHIR. Currently none of the required resources are available to developers in a published version of FHIR, only the current build.

For all three of these project implementers can only sell systems that conform to the regulations that have been imposed. The Regulators cannot establish the necessary regulation until there is some published form of the resources and technology they wish to mandate. Therefore in these three cases the demand for R5 will not come from the implementers.

4) UK dm+d (national drug database)

This has been mapped to R5 resources and needs the published standard to really proceed

5) Vulcan Accelerator and Transcelerate Projects

Covid has slowed the start of the Vulcan projects but it will get going this year. Some of the resources used in clinical research will be subject to detailed scrutiny and are bound to change quite rapidly - this has already started within the reviews BR&R have undertaken. There has also been work on FHIR done by Transcelerate that picked out changes required in resources for systems to work. These could be an R4 update rather than an a full R5 publish.