

Call for tenders' details

Title: Real World Data Subscription

Start date: 19/06/2020

Time limit for receipt of tenders: 20/07/2020

Contracting authority: European Medicines Agency (EMA)

Status: Closed

Call for tenders question list

#	Submission date	Publication date	Question subject	Question	Answer
1	01/07/2020 11:34	01/07/2020 11:38	Geographical coverage	Is there an obligation to include databases from France, the United-Kingdom and Germany in the tender?	01/07/2020 The requirements for the geographical coverage of the databases to be included in the tenders are specified in Chapter 3.2, article 4, of the technical specifications. The information provided in Chapter 3.1. regarding databases from France, the United-Kingdom, Germany and other EEA/EU countries sets out the desired characteristics of databases if databases from these countries are envisaged to be proposed in a tender. It does not provide any obligation to include databases from these countries in the tender.

Call for tenders questions summary

#	Submission date	Publication date	Question subject	Question	Answer
2	01/07/2020 18:25	06/07/2020 14:17	We have a question related to minimum requirement number 12, specifically in respect the export functionality	Remote access implies by definition that the data cannot be exported as raw data or analytical datasets, only as analytical results. Can EMA confirm that only analytical results will be exported?	06/07/2020 Exporting only the analytical results is an acceptable solution, but tenderers are requested to provide in their response the details on how this will be implemented in practice.
3	03/07/2020 17:50	06/07/2020 14:19	Extension of 3 weeks	Given the holiday period and the COVID situation we would like to request an extension of the deadline with 3 weeks. This would allow us to make sure our offer is technically and legally correct.	06/07/2020 Bearing in mind that the due date for submission of offers is 20/07/2020 which is still 2 weeks from now, the requested extension cannot be granted, thereby also taking into consideration the project planning. The holiday period has already been taken into consideration, and at this stage the ongoing COVID situation is no longer considered a critical factor impeding an economic operator's ability to prepare and submit a tender.
4	08/07/2020 15:29	08/07/2020 15:30	UK data	Our understanding is that the EMA is not looking for any more primary care databases for the UK as you have access to IMRD UK. However, would EMA be interested in hospital data linked to UK primary care data? It should be noted that the hospital data currently does not include prescribing data.	08/07/2020 Yes. However, the tenderer's attention is drawn to the technical specifications section 3.2 Minimum requirements which states that a proposal must include access to at least 3 different databases, as described under item 4 of section 3.2.