



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<dd/mm/yyyy>
EMA/658203/2022

<name and address of the applicant/ marketing authorisation holder (MAH)>
<name of the product>

Subject: Clinical Study Data submission cover letter

Dear Sir/Madam,

As per our agreement in the signed 'Clinical study data proof-of-concept pilot participation letter', a data package has been submitted for the underlying application.

The data package meets the requirements as laid out in the 'Questions and Answers about the clinical study data proof-of-concept pilot for industry'. In particular, the following is included:

<high-level summary of the content of the data package, e.g.

- list of clinical studies included
- list of files included>

Yours faithfully,

<signature>

<name and contact details applicant/MAH>

