

## Contents

<b>1</b>	<b>Objective and scope</b> .....	<b>1</b>
<b>2</b>	<b>Questions and answers (Q&amp;A)</b> .....	<b>1</b>
2.1	Can electronic submissions be sent by e-mail? .....	1
2.2	Can electronic submissions be sent by a file transfer service (FTP)? .....	1
2.3	Can electronic submissions be sent by post? .....	2
2.4	Can submissions still be sent on paper?.....	2
2.5	Is the use of a digital signature permitted on the form "BW101_10_019e_FO Confirmation electronic submission"? .....	2
2.6	Can USB sticks be submitted instead of CDs/DVDs? .....	2
2.7	Can electronic submissions be sent via a portal? .....	2
2.8	Does the "Confirmation electronic submission" form need to be signed by hand? .....	2
2.9	In what format must submissions be sent? .....	2
2.10	Where in the eDoc structure does the "Submission" form need to be filed? .....	2
2.11	Where in the eDoc structure does the scanned (pdf) "Submission" form need to be filed? ..	2
2.12	What "Submission Type" must be stated on the "Submission" form in a reply to a formal deficiency? .....	2
2.13	Does the "SA number" (service number) always need to be stated in the "Submission" form? .....	3

## Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
1.0	02.05.2022	Initial Version	dms

## 1 Objective and scope

This Q&A document aims to answer the most important questions connected with the submission of applications and documents for clinical trials. It should always be read in conjunction with the ["Guidance on the new submission process"](#).

## 2 Questions and answers (Q&A)

### 2.1 Can electronic submissions be sent by e-mail?

No, submissions by e-mail are not accepted and will be returned unprocessed.

### 2.2 Can electronic submissions be sent by a file transfer service (FTP)?

No, submissions by FTP are no longer possible (since 31.12.2021).

**2.3 Can electronic submissions be sent by post?**

Yes, electronic submissions can be sent by post. This requires the submission of a CD/DVD with the application documents and the manually signed paper form "[BW101 10 019e FO Confirmation electronic submission](#)". The submission of USB sticks is not permitted.

**2.4 Can submissions still be sent on paper?**

Yes, as an alternative to electronic submissions, paper-based submissions are also possible. This requires the submission of the complete paper documentation and a CD/DVD with the application documents.

**2.5 Is the use of a digital signature permitted on the form "[BW101 10 019e FO Confirmation electronic submission](#)"?**

No, the use of digital signatures is not permitted.

**2.6 Can USB sticks be submitted instead of CDs/DVDs?**

No, USB sticks may not be submitted.

**2.7 Can electronic submissions be sent via a portal?**

No, electronic submissions via a portal are not possible at present, although the option of submission via a portal is currently being developed.

**2.8 Does the "Confirmation electronic submission" form need to be signed by hand?**

Yes, the form "[BW101 10 019e FO Confirmation electronic submission](#)" must be signed by hand (wet-ink) and submitted in paper format. Electronic signatures (digital signatures) are not accepted.

**2.9 In what format must submissions be sent?**

Submissions must be sent using the "eDoc" folder structure. Please use the template "eDoc-file structure (ZIP file)" provided on the website for this purpose.

**2.10 Where in the eDoc structure does the "Submission" form need to be filed?**

The "Submission" form is filed as an electronic original file (no scan, no digital signature) in the folder "00F/01FM", and the manually signed last page is filed as a scan in the folder "00F/02FO".

**2.11 Where in the eDoc structure does the scanned (pdf) "Submission" form need to be filed?**

The printed and manually signed last page of the "Submission" form is filed as a scan in the folder "00F/02FO".

**2.12 What "Submission Type" must be stated on the "Submission" form in a reply to a formal deficiency?**

When replying to a formal deficiency, select the Submission Type "ANSWER to FORMAL DEFICIENCY".

**2.13 Does the "SA number" (service number) always need to be stated in the "Submission" form?**

No, the "SA number" only needs to be stated if it is known, e.g. if the number is shown on the letter concerning the formal deficiency. If the number is not known, the field can be left blank.