

**Annex 4**  
**ADDITIONAL AGREEMENTS TO THE CONTRACT MODEL**

On the one hand, Mr/Ms \_\_\_\_\_, as Managing Director of the centre,  
\_\_\_\_\_.

On the other hand, Mr/Ms \_\_\_\_\_, as \_\_\_\_\_ of the Managing Entity.

And on the other hand, Mr/Ms \_\_\_\_\_, as \_\_\_\_\_ of \_\_\_\_\_  
(hereinafter, the Sponsor).

And on the other hand, Mr/Ms \_\_\_\_\_, as principal researcher of the study, in proof of  
knowledge and acceptance.

**MANIFEST**

**I.-** That the current model contract for **observational studies with drugs** was approved by the 13 June 2019 Resolution of the General Secretariat for Research, Development and Innovation in Health and its updating requires a procedure **that is currently underway**.

**II.-** That the agents involved in performing this type of studies within the public health system of Andalusia require the updating of said contract in accordance with the current applicable regulations, specifically Royal Decree 957/2020, of 3 November, regulating observational studies with medicinal products for human use, which entered into force on 2 January 2021.

In accordance with the foregoing, the parties

**DECLARE**

**First:** That the parties wish to specify the following aspects:

- A) The references included in the contract model for performing post-authorization observational studies made to Order SAS 3470/2009, of 16 December, which publishes the guidelines on post-authorization observational studies on medicinal products for human use, published in Official Gazette No. 310, de 25 December 2009, shall be understood to be performed in observational studies with medications according to Royal Decree 957/2020, of 3 November, regulating observational studies on medicinal products for human use, published in Official Gazette No. 310 of 26 November of 2020, therefore not applying the classification of studies referred to in the contract model.

Therefore, it is expressly clarified that the articles referred to in the aforementioned model that are made to the previous regulations will be replaced by those regulating the matter in question, including but not limited to the following:

- Second clause, on party obligations, paragraph B), to article 9 of Royal Decree 957/2020, of 3 November.
- Third clause: Paragraph 3, concerning investigative team compensation, to Article 7, paragraph 3, of Royal Decree 957/2020, of 3 November.
- Tenth Clause on the publication of results to Article 6 paragraph 3 and Article 9, paragraph j), of Royal Decree 957/2020, of 3 November .

B) References made to Decree 439/2010, of 14 December, which regulates the bodies of healthcare ethics and biomedical research in Andalusia, will be understood as made to Decree 8/2020, of 30 of January, which regulates healthcare ethics and biomedical research bodies in Andalusia.

C) References to the Spanish data protection regulations shall be considered to be expressly made with reference to Organic Law 3/2018 of 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights.

**Second:** This Annex should be used by the parties until the resolution of the General Secretariat of Public Health and R&D+i in Health is published, approving the new model contract for the execution of observational studies with medicinal products in the Andalusian public health system.

And, in proof in accordance with the full content of this document, the involved parties hereby sign [...] Copies of this Annex, in the place and date indicated below / digitally on the date indicated in the electronic signature (*Note: delete the option that does not correspond, depending on whether the signature is handwritten or made electronically*).

In \_\_\_\_\_ on \_\_\_\_\_ of 20 /date of digital signature.

**By the Centre**

**By the Managing Entity**

SIGNED: Mr/Ms\_\_\_\_\_

SIGNED: Mr/Ms\_\_\_\_\_

**By the Sponsor**

**As a sign of knowledge and acceptance, the  
principal researcher**

SIGNED: Mr/Ms\_\_\_\_\_

Mr/Ms\_\_\_\_\_