

OBSERVATIONAL STUDY WITH MEDICINAL PRODUCT

- Filled **AGREEMENT** and **BUDGET template** in Spanish (may also be signed in English, but signature in Spanish is mandatory).
 - Protocol
 - Favourable opinión of the **Ethics Comitee (CEIm)**
 - **CAM** authorisation (if the study is a prospective follow-up study)
 - **INSURANCE POLICY** (must include HULP, FIBHULP, and PI)
 - **CONFORMITY OF THE CENTRE'S MANAGEMENT.** - This document is issued by our CEIm and with its issue a HULP CODE is assigned to the study.
- Please contact:

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maribel.arribas@salud.madrid.org

▪ NOTARISED OR APOSTILLED DOCUMENTS

WHO SIGNS THE AGREEMENT?	DOCUMENTATION TO BE PROVIDED
SPONSOR signs the contract on his own behalf	Powers of attorney (POA) of legal representative of SPONSOR
CRO signs the contract on behalf of SPONSOR	Powers of attorney (POA) of legal representative of CRO
	Delegation Letter from SPONSOR to CRO