

NON POST-AUTHORIZATION SAFETY STUDY WITH MEDICINAL PRODCUTS (DRUGS)

- **CONTRACT** and **BUDGET TEMPLATES** completed in Spanish (may also be signed in English, but the Spanish signature is required)
- Protocol
- Favourable opinion of the **Ethic Committee (ECRmp)**. You must contact with:

sol.gracia@salud.madrid.org

maribel.arribas@salud.madrid.org

- Qualification of the study by **AEMPS** (Spanish Medications and Healthcare Products Agency). Only if the study collects drugs data

▪ **NOTARIZED DOCUMENTATION OR WITH HAGUE APOSTILLE of:**

| WHO SIGNS THE AGREEMENT? | REQUIRED DOCUMENTATION |
|--|---|
| Sponsor signs in his own name and representation | Powers of Sponsor's legal representative |
| CRO signs on behalf of Sponsor | Powers of legal representative of the CRO |
| | Sponsor's letter of delegation to the CRO |