

## TEMPLATE 5

### RFI REQUIREMENTS FOR SAFE-BIOPHARMA-COMPLIANT CREDENTIALS USED FOR AUTHENTICATION

#### Introduction:

The following requirements should be included in a Request for Information (RFI) where information is needed about the ability of digital credential providers being considered by <Company Name> to meet the SAFE-BioPharma Standard requirements for digital identity credentials – either PKI or non-PKI or to establish that the credential provider is already certified compliant with SAFE-BioPharma Standard requirements. PKI credentials may be used either for execution of digital signatures which are compliant with SAFE-BioPharma standards or for authentication of the individual user. Non-PKI credentials may be used for authentication of the individual user either directly or through a federated identity system.

#### Requirements:

4. Non- PKI credentials: For provision of non-PKI credentials, “Is the credential provider capable of meeting the requirements of the SAFE-BioPharma Trust Framework Provider Program or is the credential provider already certified by SAFE-BioPharma or by another trust framework recognized by SAFE-BioPharma?” A list of certified CSPs and recognized trust frameworks may be found at the SAFE-BioPharma website noted below.
5. PKI Credentials: For provision of all Public Key credentials used by an individual for digital signature or authentication purposes, “Does the credential provider issue and manage by PKI credentials via Certificate Authorities (CAs) which are cross-certified with the SAFE-BioPharma Bridge CA (SBCA) AND certified compliant with EU requirements as stipulated in the current versions of ETSI Standards EN 319 401, EN 319 411 and EN 319 412?” CAs which are cross-certified with the SBCA are shown on the SAFE-BioPharma web site noted below. EU qualified CAs are shown in the EU Trust List at <https://ec.europa.eu/digital-agenda/en/eu-trusted-lists-certification-service-providers>

NOTE: The SAFE-BioPharma Standard comprises a series of documents which provide specific technical, policy and practice requirements for identity credentials (both PKI and non-PKI). These documents also include the Operating Rules for members and vendor partners for the two SAFE-BioPharma trust frameworks (PKI and non-PKI). Vendor products and services which have been certified by SAFE-BioPharma as compliant with appropriate SAFE-BioPharma technical requirements are listed on the SAFE-BioPharma website. <http://safe-biopharma.org> SAFE-BioPharma standards may be obtained by contacting SAFE-BioPharma at [info@safe-biopharma.org](mailto:info@safe-biopharma.org)