

AXSANA – SIGNATURE AND DELEGATION LOG

Protocol	AXSANA	Site ID	S E -	
Name of the PI		Site name		

PART 1: Description of responsibilities and delegation by the PI

To be signed by **all site study staff directly or specifically** involved in **study specific** patient assessment, study data collection and data entry into eCRF
In case more site study staff need to be added than the rows allocated by the hereunder table, please make copies of the blank page 1 to cover all site personnel. The original of this form should be kept in the site study binder and updated if any change in site staff occurs.

NAME	TITLE	FUNCTION (*)	DELEGATED RESP. (**)	SIGNATURE	SHORT SIGNATURE	DATE RESPONSIBILITY		PI (SHORT) SIGNATURE FOR APPROVAL
						STARTED / ENDED		

(*) **Function:** **PI** = Principal Investigator, **SI** = Sub-Investigator, **SN** = Study nurse, **OTH** = Other: please specify
 (**) **Delegated Responsibility:** **DOC** = online documentation in eCRF, coordination of QoL questionnaires & registration of patients; **SIGN** = approve, sign & send forms;
IC = Informed Consent procedure & review of inclusion and exclusion criteria; **ALL** = all study related actions; **OTH** = Other: please specify

**Please complete all fillable fields of Part 1 electronically and print it out.
 After filling in dates and signatures send a scan to Ass. Prof. Bilge Aktas:
aktas@eubreast.com and cc to esculape@axsana.com**

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PART 2: Contact details for password allocation and confirmation e-mail

E-mail addresses of staff members **to whom the following responsibilities** (DOC, SIGN, ALL) have been assigned (see previous table) should be listed in the hereunder table. In case more site study staff need to be added than the rows allocated by the hereunder table, please make copies of the blank page 2 to cover all site staff concerned.

This information is necessary to allocate the specific password/access depending on the delegated tasks. Only staff members in this list will be given specific passwords/accesses. The login & password that will be attributed are personal, not transferable, and confidential.

NAME (IN CAPITALS)	E-MAIL (IN CAPITALS)

**Please complete all fillable fields of Part 2 electronically and send it via e-mail to
Ass. Prof. Bilge Aktas: aktas@eubrest.com and cc to esculape@axsana.com**