

# Study site user manual: Electronic questionnaires

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Questionnaires measuring quality of life and arm morbidity are distributed to participants after signed informed consent: at baseline (i.e., between 4 weeks before surgery and the day of surgery) and at 1-, 3- and 5-year follow-up (+/- 2 months). Participants will primarily be asked to complete electronic questionnaires on their mobile phone, tablet, or computer. If needed, questionnaire PDFs for printout are available on the AXSANA website <https://www.eubreast.com/?Trials/AXSANA>.

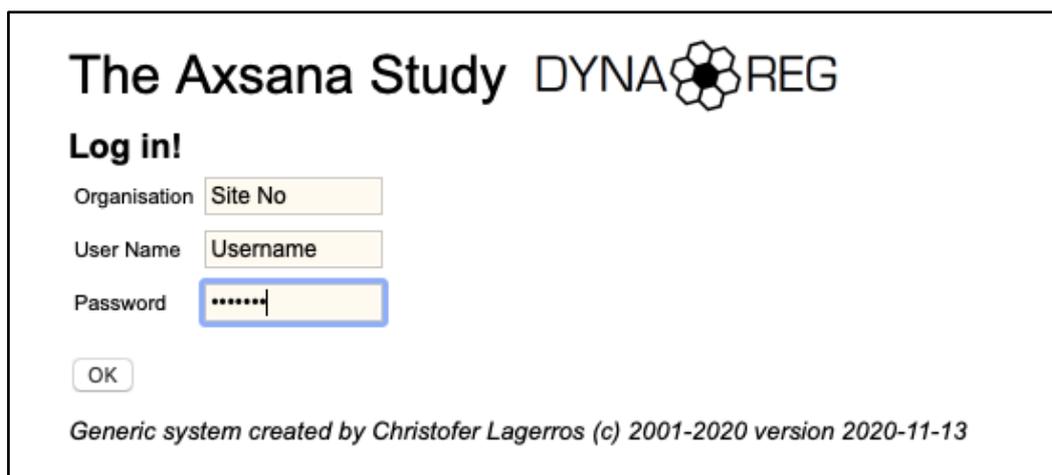
Participants should complete questionnaires within two weeks after receiving the code letter (see below). During follow-up, the site sends a postal reminder to the participant if questionnaires are not answered within one month. For the baseline questionnaire, however, no postal reminders are sent **since it has to be completed before surgery**.

How to register a new participant for electronic questionnaire and create participant-specific code letters:

1. Please open your web browser and save this link as a favorite:

<https://data.dynareg.se/axsana>

Enter your site number ("Organisation"), your individually assigned user name and your individual password. Proceed to log-in by clicking "OK".



The Axsana Study DYNAREG

**Log in!**

Organisation

User Name

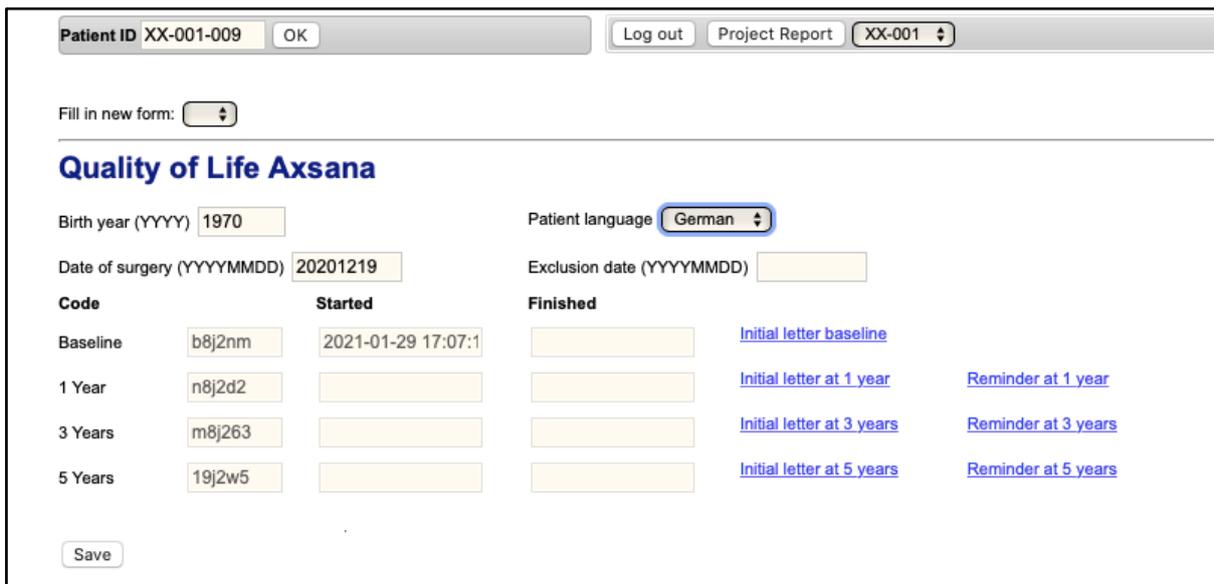
Password

*Generic system created by Christofer Lagerros (c) 2001-2020 version 2020-11-13*

2. Add a new participant by registering the Patient ID in the format shown below. In order to create a code letter for a new questionnaire, select “QoL” under “Fill in new form”.



3. Complete Birth year (YYYY) and planned Date of surgery (YYYYMMDD). If Date of surgery is changed later, please revise. You can change the language used in the code letters and questionnaires under “Patient language”. Do not forget to save data (bottom left)!



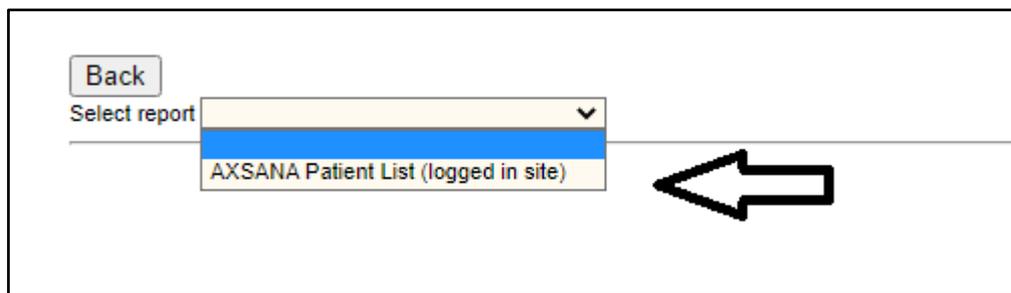
Code	Started	Finished		
Baseline	b8j2nm	2021-01-29 17:07:1		<a href="#">Initial letter baseline</a>
1 Year	n8j2d2			<a href="#">Initial letter at 1 year</a> <a href="#">Reminder at 1 year</a>
3 Years	m8j263			<a href="#">Initial letter at 3 years</a> <a href="#">Reminder at 3 years</a>
5 Years	19j2w5			<a href="#">Initial letter at 5 years</a> <a href="#">Reminder at 5 years</a>

4. Click on the blue link with the relevant code letter (Initial letter/Reminder; correct time point i.e., baseline or follow-up 1, 3, 5 years). A new page will open showing the code letter itself, which you print out and hand over or post to the participant.

To view Project Report:

**Please select the report: “AXSANA Patient List (logged in site)”.**

The Project Report shows a list with all participants enrolled at your site. Each participant corresponds to one line, where details on when the next questionnaire is due are shown. Completed questionnaires are marked with a green tick box, uncompleted questionnaires with a red “Not completed”. If a participant drops out of the study, you need to enter the date of exclusion on the participant front page. In the list below, this participant will be marked by “Excluded from study”.



Click on the Patient ID Number and you will be directed to the participant-specific page for printing Initial letters or Reminders.

Patient ID	Date of surgery	Exclusion Date	Baseline Status	1 Year planned	1 Year Status	3 Years planned	3 Years Status	5 Years planned	5 Years Status
<a href="#">XX-001-001</a>	2020-12-01		2021-01-19	2021-12-01	2021-01-20 (Not completed!)	2023-12-01		2025-12-01	
<a href="#">XX-001-002</a>	2019-11-05		Missing!	2020-11-05	Missed interval	2022-11-05		2024-11-05	
<a href="#">xx-001-003</a>	2019-12-12		Missing!	2020-12-12	Time to fill in	2022-12-12		2024-12-12	
<a href="#">xx-001-004</a>			Missing!		-		-		-
<a href="#">xx-001-005</a>	2020-06-07	2021-01-26	Missing!	2021-06-07	Excluded from study	2023-06-07	Excluded from study	2025-06-07	Excluded from study
<a href="#">xx-001-006</a>	2020-09-09		Missing!	2021-09-09		2023-09-09		2025-09-09	
<a href="#">XX-001-009</a>	2020-12-19		Missing!	2021-12-19		2023-12-19		2025-12-19	
<a href="#">xx-001-025</a>			Missing!		-		-		-

If one of your patients prefers using paper questionnaires, please send the completed questionnaires to Ms. Jana Shabbir either via e-mail or fax: [J.Shabbir@klinikum-esslingen.de](mailto:J.Shabbir@klinikum-esslingen.de) or +49 711 3103 3069.

**Important: Patient ID and date should be clearly visible on the questionnaires!**

In case of questions about questionnaire content, please contact: [matilda.appelgren@ki.se](mailto:matilda.appelgren@ki.se)

In case of questions about user name, passwords or other technical issues regarding this electronic survey, please contact: [chrille@lagerros.se](mailto:chrille@lagerros.se)