Confirming design changes to the study
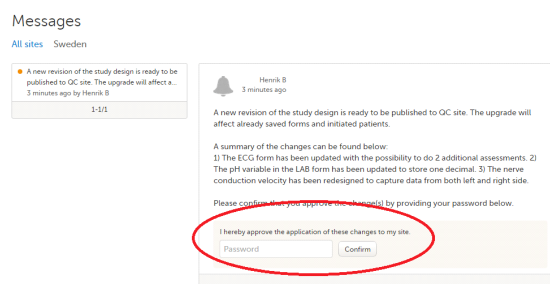
1 **Why is this necessary?**

- Changes to the eCRF can occur during the course of a study. Normally this is due to an amendment. The definition of an amendment is that it is a change in the protocol from a specific time-point. This means that already saved forms and visits should not be affected by the amendment.

  Sometimes there is however a need to change the design/content of already saved forms and visits, for example when there is an error in the configuration (a missed question, a spelling error etc). For these changes to be applied on already saved data, a confirmation is needed from the site staff.

2 **How is a design change flagged?**

- Whenever there is a need to change already saved forms, a message on the start page will appear for the site to acknowledge. The message will summarize the changes to the eCRF and a confirmation (through a password) is needed before the saved forms will be upgraded to the new version.

- Any action required after the confirmation has been given is displayed though issues, the red "i" icon. For example, if an additional mandatory question has been added to a form that was already saved, the issue icon will be displayed for all these forms.

3 **What happens if I don't do anything?**

- If no confirmation is given, the forms will keep the old version. You can however expect a reminder from your local monitor that a confirmation is expected.

4 **Who can confirm?**

- Any user on the site with the privilege to save data can confirm this message. Once confirmed, the date and name of the user who confirmed will be displayed in the message.