

Newsletter November 2017



Dear RESURGE Study Team

Thank you for your cooperation in 2017! We were able to open 5 new centres this year and have now a total of 9 centres recruiting.

➤ Recently opened site

Basel

➤ Resurge Sites

Open Recruited	Bern	Lausanne	Geneva	Zurich	Aarau	Lugano	Milano	Innsbruck	Basel
	11	3	-	-	1	-	-	-	-

About to open	Giessen, Erfurt
Planned for early 2018	Münster, Luzern, Madrid, Mainz, Nijmegen

➤ Patient follow up

We have created a follow up check list for easier handling of patient follow ups. We encourage you to start using the list to easily keep track on all documents needed on each follow up. If you have additional questions or concerns on data handling, please let us know and we will try to make processes as smooth as possible for you.

➤ Protocol Amendment

Change in reporting of SAEs: **New Text**

“All local PIs must report all SAEs where relatedness to intervention is probable or definite and death independent of any intervention immediately (maximum of 24 hours) to the study coordinator. ~~and to the local EC within 15 days.~~ SAEs and death, **where relatedness to intervention is probable or definite**, must be reported to the local EC within 15 days.

The study coordinator reports all received SAEs, **where relatedness to intervention is probable or definite**, to the lead CEC within 15 days.”

➤ Contact Details

Please do not hesitate to contact us if you require any assistance or have upcoming questions.

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