



New protocol version coming into action

Dear Investigators and Study Teams,

This is to inform you that **Protocol Version 2.0 (01.01.2026)** has been approved in CTIS. The **implementation of this protocol version**, including the country-specific addenda for Norway, Germany, and the Netherlands (where applicable), **can now begin**.

This announcement applies only to EU countries that completed the Site Initiation Visit before 15.06.2026 and are already open for recruitment. All affected sites have received an email with the updated study documents. Please ensure that these documents are:

- **Printed and filed in the Investigator Site File (ISF)**
- **Made available to all delegated study team members**

Required training

We kindly ask all delegated study team members to complete training on:

- **Protocol Version 2.0 (01.01.2026)**
- **Protocol Addendum Version 1.0 (01.01.2026), where applicable**

Training documentation

We kindly ask you to **document the training** in the **Training Log (ISF Section 10)**. Please ensure that:

- The training topic is listed as **Protocol Version 2.0 (01.01.2026)** and, where applicable, **Protocol Addendum Version 1.0 (01.01.2026)**
- The training type is recorded as "**Self-study**"
- The Training Log contains one entry for each delegated study team member, and each person signs both required signature fields
- The training is **completed, signed, and dated before 03.08.2026**

The completed Training Log must be submitted **before 03.08.2026**, as Protocol Version 2.0 becomes effective on that date.

Trial progress

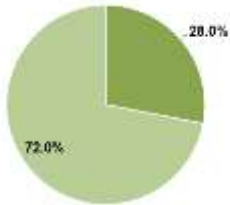
We have received **positive ethics approval from the UK** and are still waiting for the final MHRA approval. We are **eager to plan site openings across UK in the summer months**.

In parallel, we are **currently starting trial sites in France and further European countries**.

Our global trial network is growing steadily - many thanks to all sites!



Finally, we are delighted to share that **more than 250 patients have now been randomized**. Thank you for your continued dedication and support!



Keep up the pace and reach out to us with any questions, concerns or hurdles - we are happy to help you!

DO-IT Principal Investigators	Trial Coordination / Management	Contact details
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Thank you for your continued commitment and collaboration.

Recruit. Care. Cure. DO-IT!

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