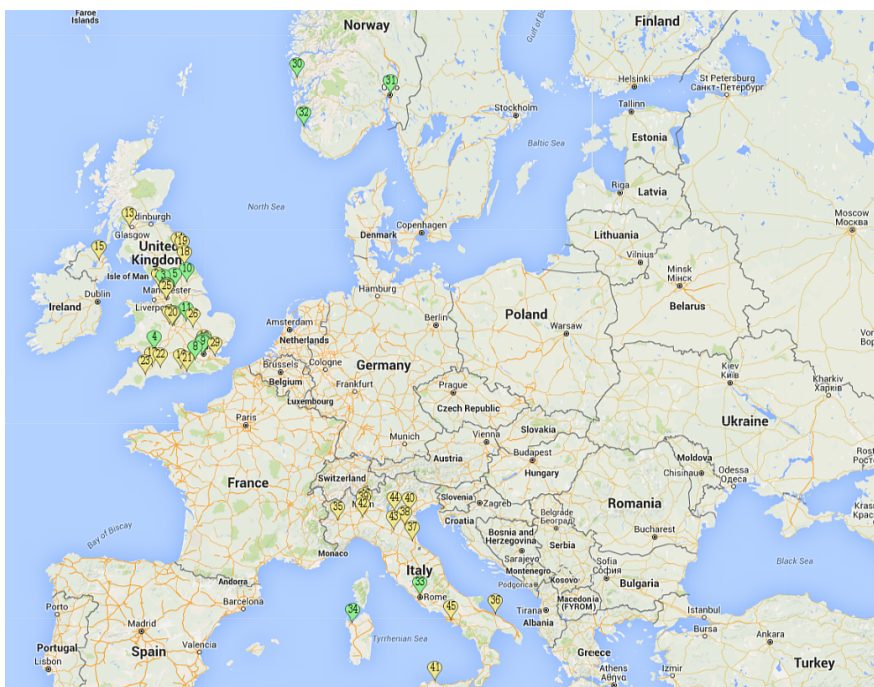




Welcome to the first PRISM trial newsletter. Thank you to everyone who has contributed to the trial so far. PRISM opened in February 2016 and we now have 16 sites open across Italy, Norway and the UK. We are very pleased with the progress and we are currently meeting our planned recruitment targets. We hope to open a wave of new sites in the coming weeks and months.

Patient recruitment

Site Name	Total	In Past 30 Days	Data Complete (%)
Sapienza Universita di Roma	35	0	84.8
Oslo University Hospital	32	12	66.7
The Royal London Hospital	21	8	83.3
Heart of England	16	8	85.7
Bradford Teaching Hospitals	15	7	80
Università degli Studi di Sassari	13	3	100
Royal Surrey County Hospital	11	9	100
Leicester Royal Infirmary	10	9	n/a
York Hospital	10	7	n/a
Royal Blackburn Hospital	6	3	0
Royal Gwent Hospital	5	2	0
The Royal Marsden	4	3	0
Haukeland University Hospital	3	3	n/a
The Christie	3	3	n/a
University Hospitals Birmingham	2	2	n/a



 open

 in set-up

The green light to recruit

Once we perform your Site Initiation Visit we need to ensure we have all the correct information from you before activating your site:

- Localised documents
- PI's Curriculum vitae*
- PI's GCP certificate*
- Signed protocol agreement version 1.5
- Completed delegation log
- Completed SIV checklist*
- Local Institutional approval (local R&D/HRA approval)*
- PI registration on the PRISM database

Once all this is in place we can open your site to recruitment.

*UK sites only

FAQs

1. What counts as 'open surgery'?

For PRISM, open surgery is defined as any procedure where the incision is larger than that required to remove the surgical specimen. For example, if a laparoscopic port incision is extended to externalise a loop of bowel, or made larger than needed to remove the specimen bag, then we would consider this to be open surgery. If you are in doubt, we recommend discussing the planned surgical technique with your surgical colleagues.

2. Is nausea an adverse event?

Nausea is not an adverse event, but vomiting is an adverse event. If CPAP is stopped or interrupted for a prolonged period as a result of nausea, please record this as a protocol deviation. Is the patient vomits as a result of CPAP, please record this as an adverse event and complete a protocol deviation form if required. All adverse events should be verified by the PI or suitably qualified nominee (doctor) as probably or definitely related to CPAP. Please record on the adverse event form (an online database) that this has been verified and state the name of that person.

Contact information

One of the best ways to keep up to date with trial news is on twitter.

Follow us: @prismtrial 



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