Issue 5 | MAY 2023

ACTION Group

ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS

Acute **M**yocardial infarction **U**pbound to percutaneous coronary intervention, immediately (STEMI) or in the **N**ext three **D**ays (NSTEMI), and randomized to **S**ubcutaneous **E**volocumab or **N**ormal strategies to reach guidelines LDL objectives in the real-world - The AMUNDSEN-real study

AMUNDSEN real

www.action-groupe.org

Editorial:

Congratulations to Prof. Emile Ferrari and his team in Nice. They are leading the way now in terms of recruitment. Italy is speeding up its recruitment with excellent performance from 3 Italian sites.

Dr Picchi (Grosseto) Prof. Bolognese (Arezzo), Prof. Bouletti (Poitiers), Prof. Ferrari (Nice), all have included more than 20 patients in the past three months. It is impressive to see that 97% of open sites are active! We need more patients from the centres which have started but not enrolled regularly. If you have randomized once or twice you can do it again! Please, talk to your colleagues and reactivate the study in your center! We expect Germany and Poland to start in the coming weeks. Every patient counts, every week, every week-end, every night! We will organize an investigator meeting at ESC. For those of you present in Amsterdam, stay tuned, we'll come back to you with an invitation!

See you soon then!

Pr Gilles Montalescot

Study update: 683

Welcome to the sites of

402 - Ospedale Sant'Anna Ferrara, Dr Campo

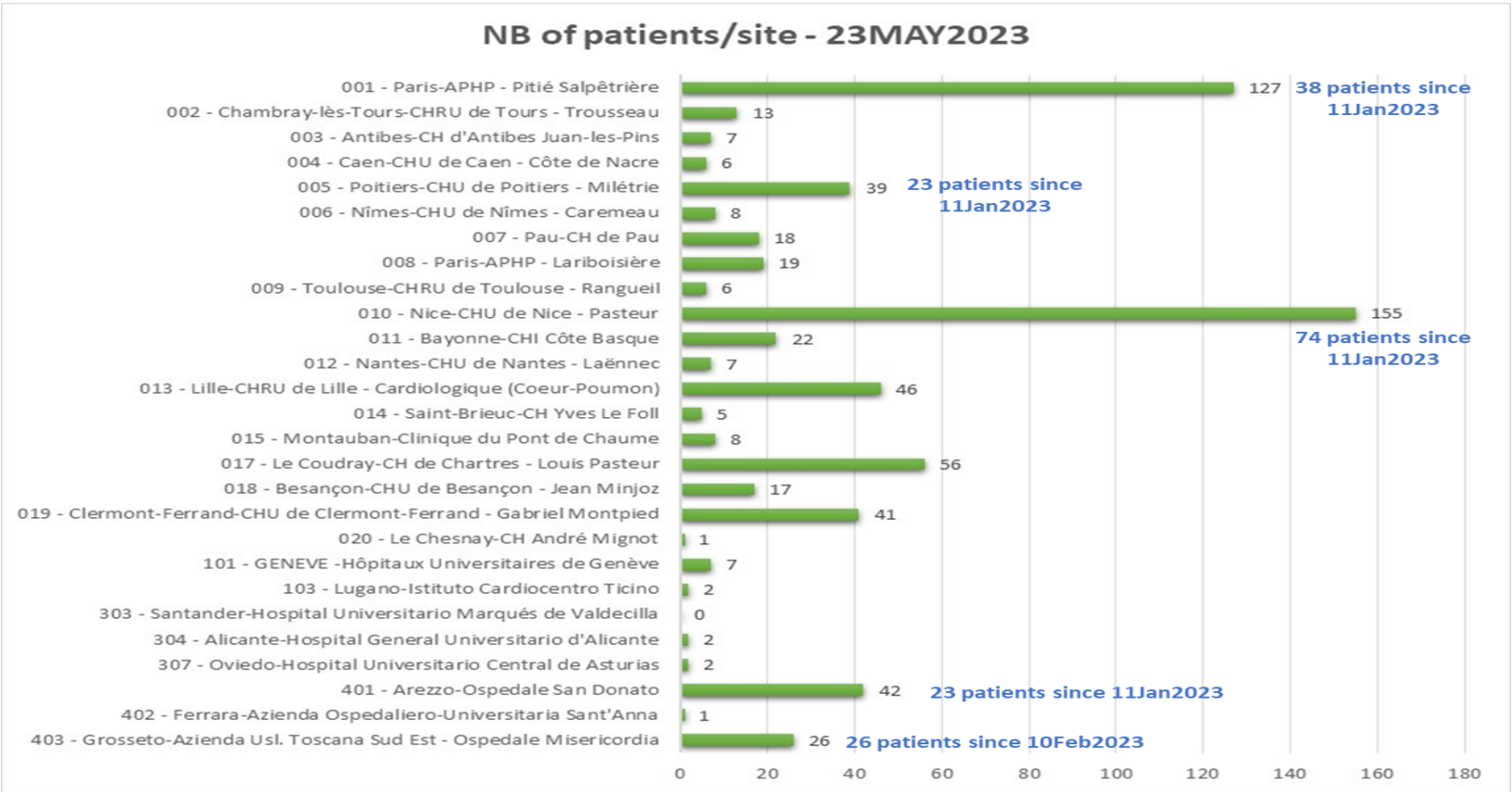
403 - Ospedale Misericordia Grosseto, Dr Picchi

303 - Hospital Marqués de Valdecilla Santander, Dr Royuela-Martinez

304 - Hospital Alicante, Dr Ruiz-Nodar

Site update:

- 27 opened
- 26 active sites
- 7 sites to open in June



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News:

- **eCRF:** guideline of completion available on line => Information—Support

- **eCEC: You can start to upload your source documents on the Clinigrid plateform**

The following endpoint events should be reviewed by a blinded central Clinical Events Committee

- Death of any cause
- Acute coronary syndrome
- Cerebrovascular event
- Coronary revascularization
- Hospitalization for other cardiovascular reason (Other cardiac reason than acute coronary syndrome or coronary revascularization leading to an admission, hospitalization or prolongation of existing hospitalization.)

These events are entered in « adverse events » section of the eCRF and transferred automatically to the eCEC platform.

Your CRA will

- contact you to determine the list of users to create their access
- send to you the Endpoint Source Document Submission Guide.

Study contacts:

For any question, your primary point of contact is your monitor:

FR: **Amel CHAMAM**
amel.chamam@aphp.fr

CH/DE/ES/IT/PL: **Amel MEKALICHE TAMENDJARI**
amel.mekaliche@clinact.com

You can also contact us at the ACTION group:
amundsen@action-groupe.org or gilles.montalescot@aphp.fr

DSMB:

- 3rd meeting done on 04Apr2023
- Recommendation to continue the trial without modification

Don't forget:

- **Enter data** for patients who have completed a follow-up visit or finished the study
- In the treatment arm **avoid treatment interruption**. If treatment has been stopped it can be restarted at any time during follow-up.
- **LDL values** at inclusion can be values **within 3 months before randomization or just after in case of emergent PCI**
- **ESC/EAS guidelines should be followed** => see diagram below