

SonaCare Medical HEAT Registry Update April 26, 2018

USA Recruitment Arm

Patients enrolled to date	120
Expected enrollment by end of Q2	220

Sites currently enrolling patients	2
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Sites signed up to enroll	25
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Maximum follow-up	2 years
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European Recruitment Arm

Patients enrolled to date	2,200
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Maximum follow-up	5-7 years (estimate)
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Oversight

- A working group in the US that consists of ~ seven individuals with two Chairs that meet by phone every two months and in person two-three times per year.
- Data only accessible to individual/site entering the data or to others following permission from data owner
- Publication timing, participation, structure, under purview of the working group
- SCM provides administrative support but has no direct access to data
- Quality of data not reviewed yet, working group evaluating how to assess/implement/ enforce

Impediments to enrolling

Each U.S. site has keep data in its own proprietary database format. We have worked through a process to create “translators” for each site that will take their data and put it in the proper format and location in the HEAT registry structure. This has been done for the first two sites and is being extended to all others with SCM medical covering the cost, the work being done by the registry implementation team in the U.K. Moving forward sites will either use HEAT for their database or will continue to enter in their own database with the site-specific translator used to also enter into HEAT.