

NEWS BITES:

STUDY EXTENSION

We have applied for a 6-month study extension. The NIHR has asked sites to contine to recruit as normal (i.e. past the earlier 30th of June end date) whilst they finalise the extension. Watch this space for updates and keep recruiting!

STAYIN TOUCH! WITH WHATSAPP

We have launched a WhatsApp Community Group for everyone involved in PIC Bone.

This is for <u>direct communication</u> between sites and study team, troubleshooting queries on the go, and receiving <u>useful updates</u>.

There are group chats for general queries and Assoc Pls. Feel free to join only ones relevant to you.

Scan the QR Code to join!





SA01 DOCUMENTS

Please remember to use **V2.0** of both the Parent Information Sheet and Consent Form!



Message from Tim & Dan:

It's been another amazing month for PICBone! Retrospective recruitment passed the 5,000 mark! "Only" another 1,000 left to go. Prospective recruitment has also accelerated. With the extension, up to the end of the year, we should reach our magic targets. Please keep the good work going, we are 99 getting there!!



API Scheme - LAST CHANCE. With the study extension, we are encouraging you to recruit and replace your Associate Pls. Each site can have up to 2 APIs at any one time!

The API scheme is a six-month in work-training opportunity for healthcare professionals who are new to research. APIs reduce the workload of PIs and increase site recruitment. APIs will receive a certificate of Associate PI status, which is endorsed by the NIHR and Royal Colleges.

If you have someone in your team who is interested in becoming an API or if they would like to speak to someone who has recently completed the scheme, please get in touch with us!

USEFUL REMINDERS:

Outstanding eConsent Forms

If a child and their parent/guardian has agreed to consent to the study, but has not yet completed the eConsent form, please contact them and ask them to complete this. If they no longer wish to participate in the study or you are unable to get in contact with them, please email the PIC Bone inbox so we can mark this on the database.

Site Queries

We routinely send out site queries each month. Please complete outstanding CRFs and resolve data queries on the resolve issue tab on REDCap.

We have recently sent sites a list of eConsent sign off's that were completed in 'form mode', rather than in 'survey mode' on REDCap. Completing the eConsent in 'survey mode' ensures that the families receive a copy of the consent form. For those completed in 'form mode', please send a copy of the eConsent form to the families by email and let us know when it is completed.

Also, let us know if there are changes to your site team and anyone needs adding/removing from REDCap.









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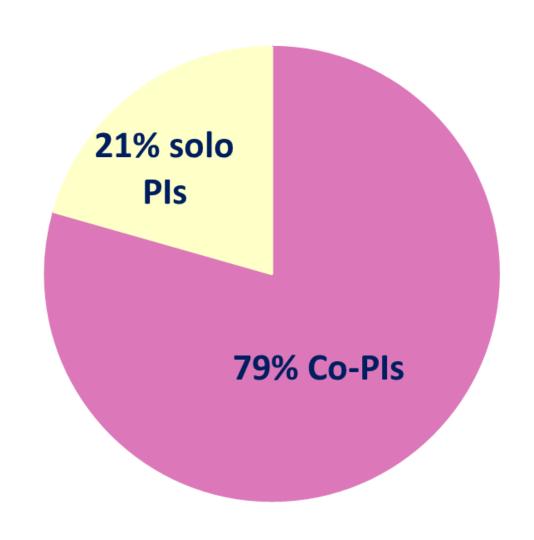


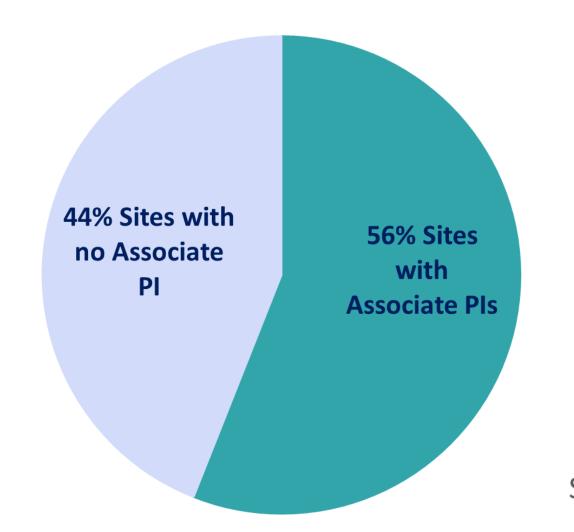
PIC BONE POSTER:



Congratulations to Anjali and the team who won Best Poster Prize at the UK Trial Manager's Network 2024 conference celebrating PIC Bone's Co-Pls and Associate Pls who are great for sites and great for recruitment!

Percentages of Co-Principal Investigators and Associate Pls in the PIC Bone Study as of 28 May 2024





RESULTS AND CONCLUSIONS

Sites with at least one API recruited 2.1 times more participants than sites without an API, which was statistically significant. The 27 sites with Co-Pls recruited 1.3 times more participants than the 7 sites with only one PI, but this was not statistically significant.

The training of APIs builds the clinical research workforce and leads to increased recruitment of patients and study productivity. Overall, a teambased approach to study organisation and recruitment have been successful in the PIC Bone study.

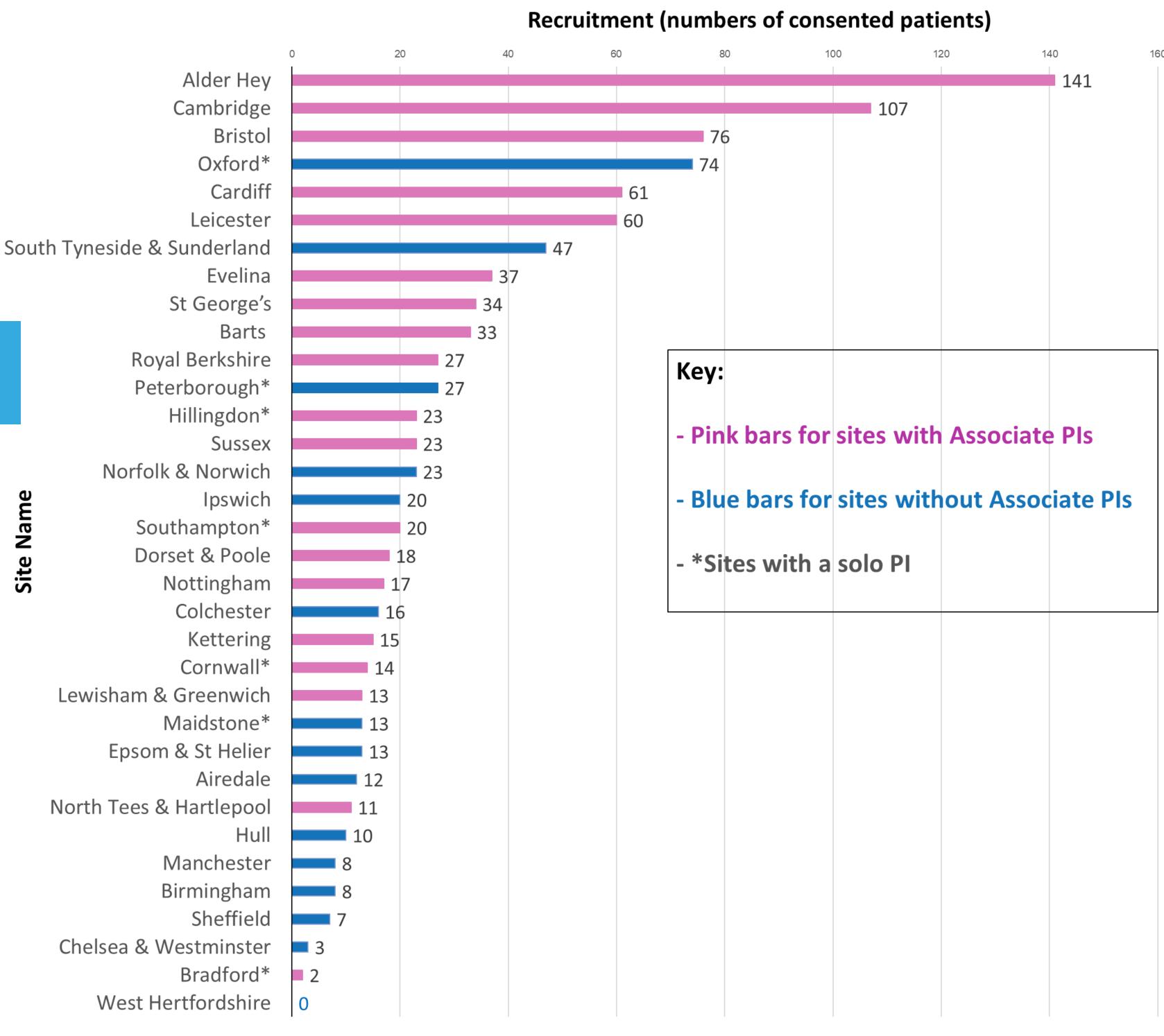
FAQ of the Month:

We have received a few emails this month querying whether participants can be recruited to the study if they have a history of trauma. As a result, we've updated the FAQ document to be sent to all sites soon. Please see the updated guidance below:

Q: What should we do if the patient's history changes at a subsequent A&E visit and now there is a history of trauma to account for the child's joint pain? Should we now exclude the patient from the study?

A: There is often a history of minor injury in children with suspected bone and joint infection. If infection is in the differential diagnosis then these children should be recruited to PICBone. If it later becomes clear that their symptoms were caused by the injury, then their outcome should be under B (Definitive exclusion of BJI diagnosis). Children with injuries that are apparent to be the cause of symptoms at initial presentation should be excluded, as dictated by the PICBone protocol.

Recruitment to the PIC Bone Study by Site and PI Status as of 28th May 2024











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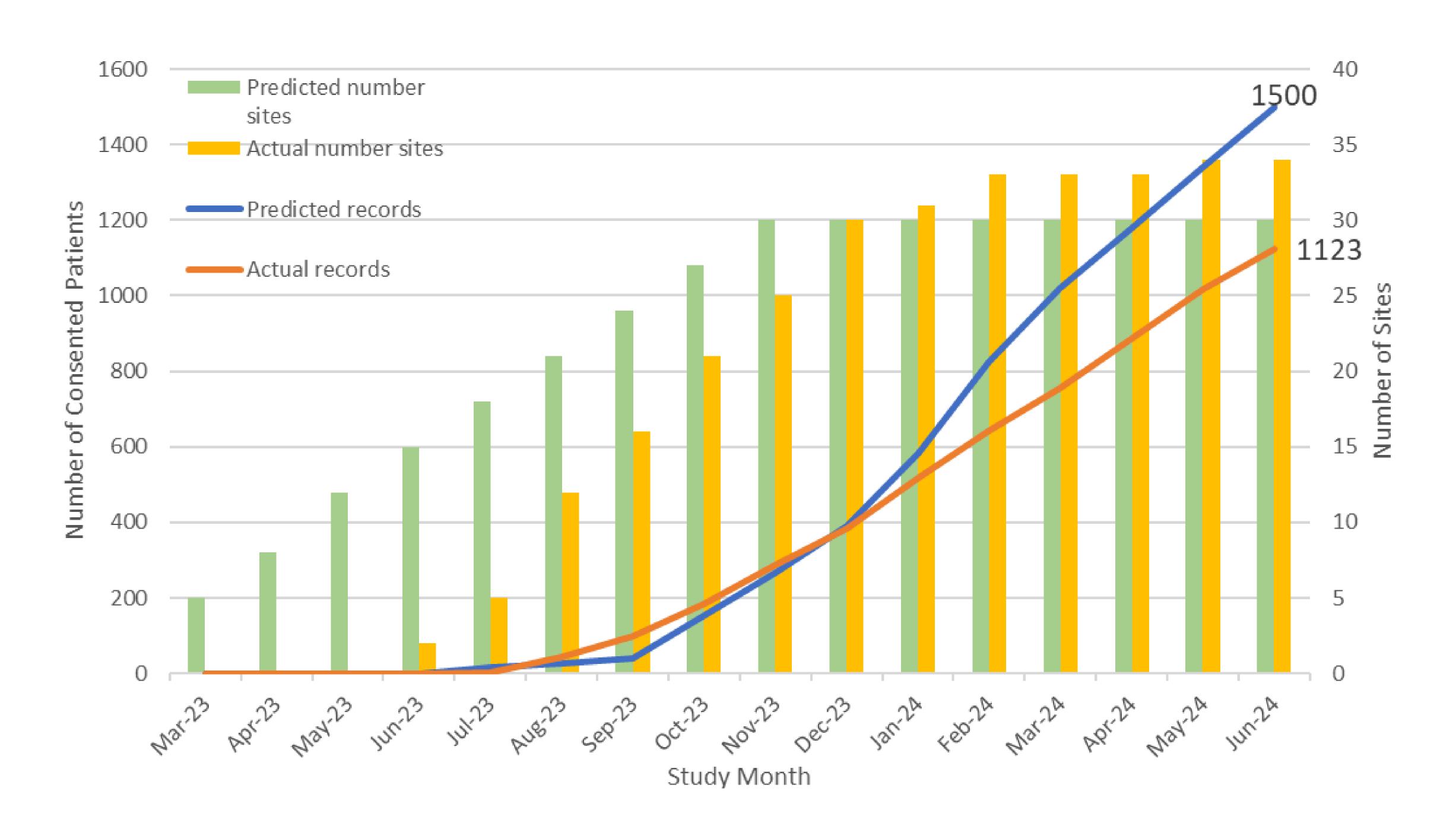


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Recruitment Updates: Study Charts

Prospective Study Recruitment as of 25 June 2024



Retrospective Study Recruitment as of 25 June 2024

