CREATING A GENERIC SOLUTION

The Bristol Trials Centre, in collaboration with other CTUs, have successfully bid for NIHR CTU Support Funding to develop a generic electronic trial management system: Mango Trial Management

Aims:

- To develop a generic system to streamline coordination of multiple trial types
- System to include the ISF & delegation log, and interaction with patient databases
- System can be easily used on desktop and mobile devices, increasing accessibility

Output: A highly configurable system available to other CTUs, which can be implemented with little/no local IT support and at minimal running cost

Timeline: Target to release first version May 2022

ELECTRONIC SYSTEM REQUIREMENTS

- Secure log in and role-based permissions
- Audit trail and regular back up
- Tested and validated
- User training documentation
- Ensues sites have full control of their ISF, and can be provided with a copy for archiving
- CTIMPs: Ensure the system does not extend the time of the inspection
  - Mapping system for where documents are stored
  - Read-only role for inspector/monitor access
  - Easy to use system to minimise/remove need for training of inspector/monitor

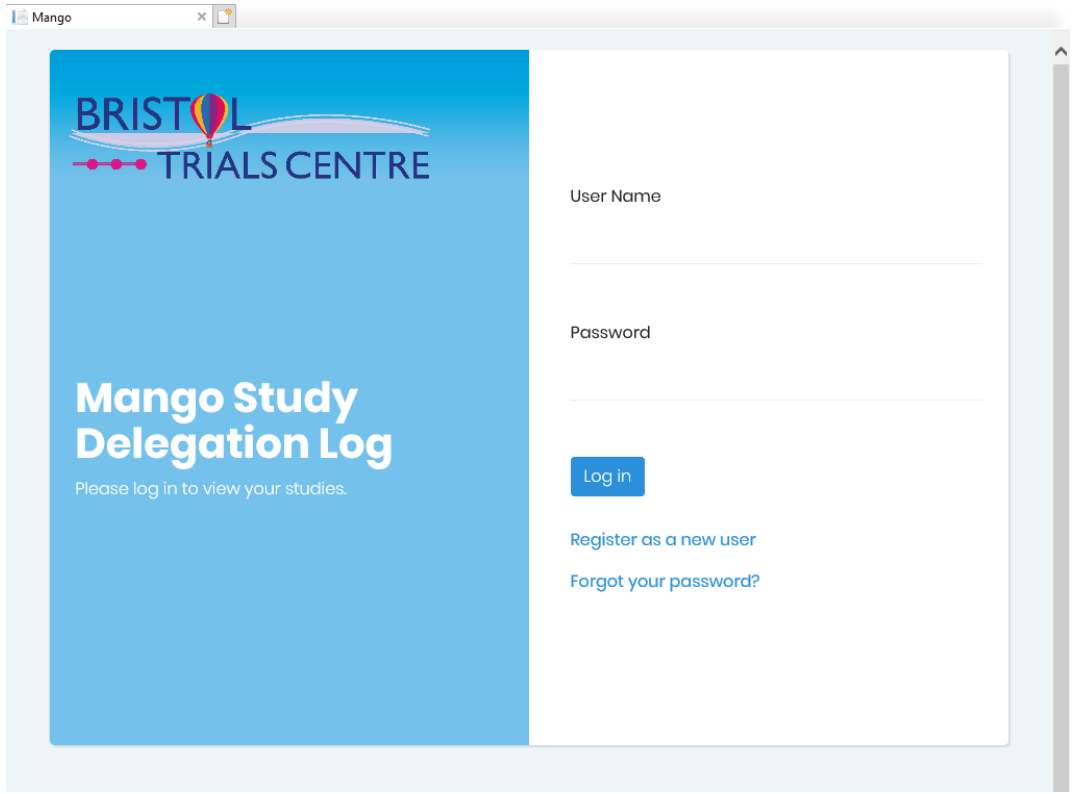
https://mhrainspectorate.blog.gov.uk/2015/07/30/inspecting-clinical-trials-the-trial-master-file/?utm_source=Blog&utm_medium=forum&utm_campaign=Inspectorate%20blog

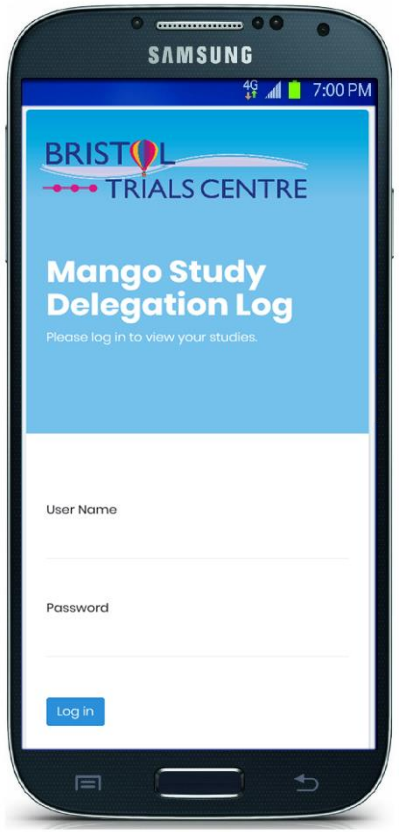
Medicines & Healthcare products Regulatory Agency

INPUT FROM THE SITE STAFF SURVEY

CONS OF PREVIOUS SYSTEMS	MANGO SYSTEM SOLUTION
➢ Need to remember passwords	➢ One password to access Mango system - used for all studies user has permission to access
➢ Some documents still on paper	➢ The system will follow MHRA guidance relating to use of electronic signatures ➢ Future releases aim to include electronic SIV logs and training records
➢ System can be slow	➢ More modern, streamlined solution

MANGO SYSTEM PREVIEW





Mango

Hello cappelh! Logout

MAIN

- Home
- Studies
- Reports

MAINTAIN

- Maintain Studies
- Study Fields
- Lists

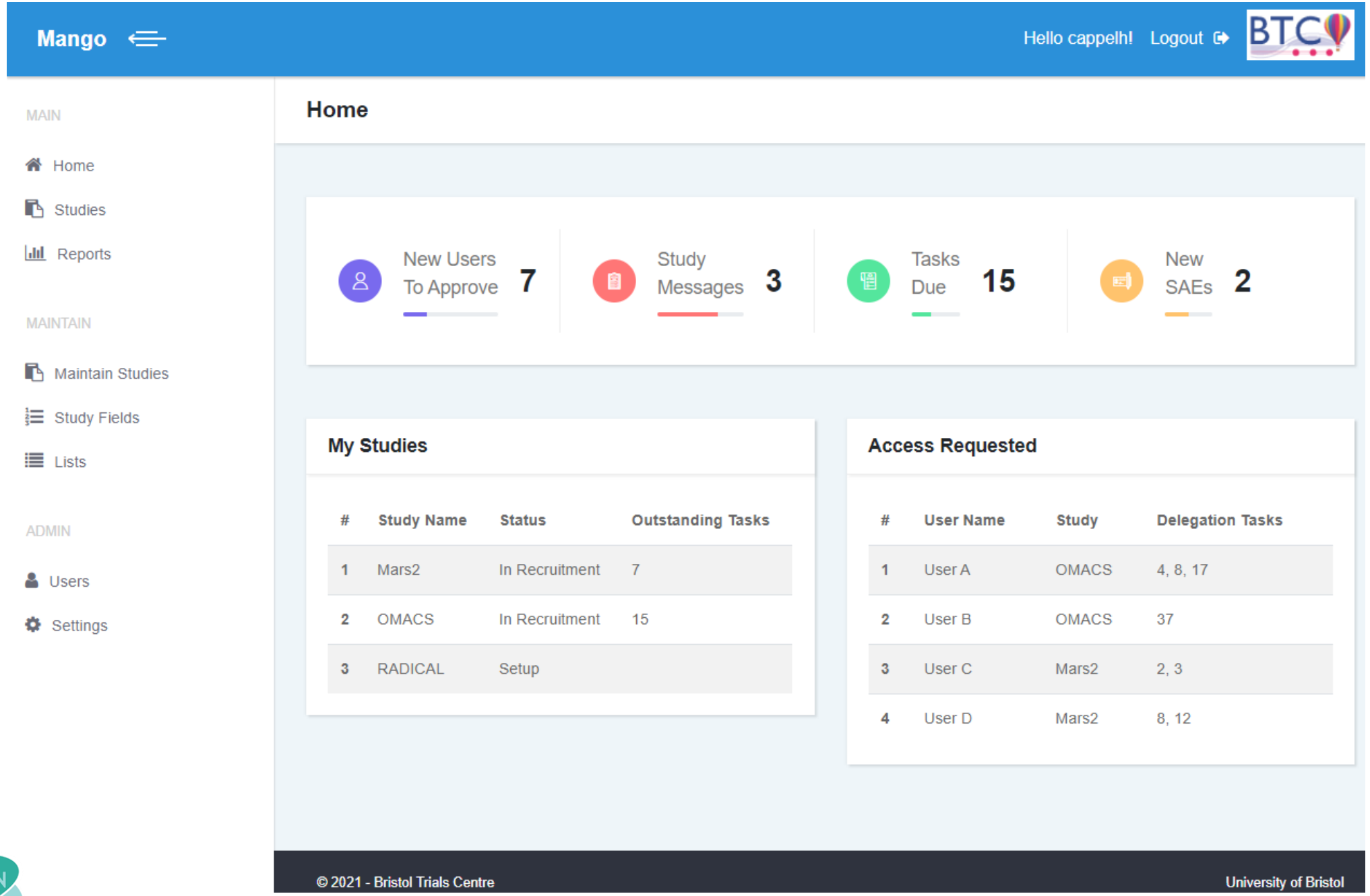
ADMIN

- Users
- Settings

My Studies

Request access to another study

Study Name	Logo	Status	
Romio	ROMIO	Set up / Not yet recruiting	Details
test	NIHR | National Institute for Health Research	Set up / Not yet recruiting	Details
BTC Test	BTC	Completed	Details
Another test	BRISTOL TRIALS CENTRE Mango Study Delegation Log	Recruiting	Details
Mars2		Recruiting	Details


Mango
Hello cappelh!
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Study Fields
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Home
New Users To Approve 7
Study Messages 3
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Study Name Status Outstanding Tasks
1 Mars2 In Recruitment 7
2 OMACS In Recruitment 15
3 RADICAL Setup
Access Requested
User Name Study Delegation Tasks
1 User A OMACS 4, 8, 17
2 User B OMACS 37
3 User C Mars2 2, 3
4 User D Mars2 8, 12
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