FAMOUS
Site Selection Questionnaire

Section 1: General Information

Organisation Name	
Department Name	
Head of Service	
Address Telephone number Email address	

Section : Trial Population and Patient Pathway in your Adult Hearing Aid Service

The trial population are adults (≥18 years) with hearing difficulties, being provided with conventional, acoustic NHS hearing aids for the first time. Each site will need to deliver the allocated treatment to all patients identified for a first-time hearing aid fitting over a 3 month period.

Note: when answering the below the term 'audiology service' includes all audiology settings in your organisation that will participate in the trial as one site.

Before the impact of Covid-19, on average, how many new, first time adult hearing aid patients did your audiology service fit each month?	
Currently, on average, how many new, first time adult hearing aid patients does your audiology service fit each month?	
Does your site currently identify and agree individual needs and develop individual management plans (e.g. using COSI or other tools)? Does your site measure patient reported outcomes (PROMs) based on individual needs? (e.g. using COSI or other PROMs)?	☐ Yes ☐ No
If an Individual Management Plan is not developed with each patient, is the audiology team willing to adopt the COSI if randomised to intervention arm?	☐ Yes ☐ No
Briefly summarise any areas where your local standard practice deviates significantly from adult hearing aid fitting procedures in accordance with UK professional guidelines (BAA/BSA/NICE)	
Is your site willing to adopt the research protocol follow-up and monitoring practices for all patients over a 3 month identification window if randomised to the intervention	☐ Yes ☐ No ☐ Unsure

arm of the trial (note: this is a cluster randomised trial, so the sites will be randomised, not the individual patients).	

	Before the pandemic Circle all that apply	Currently Circle all that apply	Likely practice from January 2022 onwards Circle all that apply
Follow up after first HA fitting	FORMAT None remote (tel or video) in person both remote or in person other, please specify	FORMAT None remote (tel or video) in person both remote or in person other, please specify	FORMAT None remote (tel or video) in person both remote or in person other, please specify
	TIMING Between 0-6 wks Between 7-12 wks After 12 wks	TIMING Between 0-6 wks Between 7-12 wks After 12 wks	TIMING Between 0-6 wks Between 7-12 wks After 12 wks
	CONTENT Summary of content covered in FU:	CONTENT Summary of content covered in FU:	CONTENT Summary of content covered in FU:
Ongoing support	No ongoing support Open access repair/support service Booked repair/support service Volunteer support	No ongoing support Open access repair/support service Booked repair/support service Volunteer support	No ongoing support Open access repair/support service Booked repair/support service Volunteer support
Monitoring	Routine evaluation of PROMs Targeted invitation for 3 year review Universal invitation for 3 year review Self-referral anytime for review	Routine evaluation of PROMs Targeted invitation for 3 year review Universal invitation for 3 year review Self-referral anytime for review	Routine evaluation of PROMs Targeted invitation for 3 year review Universal invitation for 3 year review Self-referral anytime for review

Section 3- Local Support for the Trial

Have you obtained agreement in principle to undertake the trial from the following within your organisation?: • Head of Service/Lead Audiologist (or equivalent) • Audiology Service delivery manager (if applicable)	☐ Yes ☐ No ☐ Yes ☐ No ☐ n/a
Are all stakeholders within your organisation willing for your site to be randomised to either arm of the trial (usual care or 4 step intervention arm)?	☐ Yes ☐ No ☐ Unsure
If randomised to the intervention arm , will your site be able to adapt pathways and workload to undertake additional face-to-face visits (week 6 face to face visit) and monitoring activities (7 day check-up via phone or post) for a period of 3 months (trial Excess Treatment Costs (ETCs) costed as per ACORD and as part of the research grant)?	☐ Yes ☐ No ☐ Unsure

Section 4- Experience of the Audiology Service (improvement and research)

Although previous research experience is not a requirement to be involved in the trial, we are interested in details of any previous research or service improvement that your audiology service has been involved in.

Please briefly describe any previous involvement that your audiology service has had in service improvement.	
Please briefly describe any previous involvement that your audiology service has had in research.	
If your service has recruited participants to a study or a trial, please give the names of the trial.	
Is your department currently recruiting into any other clinical trials/studies, or do you have concrete plans to recruit into any other trials/studies at the same time FAMOUS would be running at your site?	☐ Yes ☐ No
If yes, are these trials/studies recruiting the same population (i.e. adults fitted with a first-time hearing aid.)?	☐ Yes ☐ No
Please provide names/acronyms of these trials/studies	☐ n/a

Section 5 – Research support

Does your organisation employ any research audiologists?	☐ Yes ☐ No ☐ Unsure
Has your department previously had or does it currently have access to research support from dedicated research staff employed by your organisation or the Clinical Research network (tick all that apply)?	☐ Yes- organisation Research Staff ☐ Yes- CRN Research Staff ☐ No ☐ Unsure
Please provide the contact details of someone in your organisation's R&D department who will work with the clinical trials unit on the local approval and set-up of the trial:	

LOCAL R&D SUPPORT: Site coordination, administrative activities and research support will be required to deliver this trial at each clinical site. Please provide details of who from your R&D department of research support teams *may be available to support the coordination of the t*rial at your site, if selected, and give details of their research experience.

If you do not currently do research in your department, or haven't for a long while, you may want to discuss this with your local R&D department and local CRN to see what research support could be put into place for a portfolio adopted study.

Name and Job Role	Email address	Years' experience	Funding
		☐ <1 year ☐ >1 year ☐ >3 years	☐ CRN ☐ Trust / Dept ☐ Other
		☐ <1 year ☐ >1 year ☐ >3 years	☐ CRN ☐ Trust / Dept ☐ Other
		☒ <1 year ☐ >1 year ☐ >3 years	☐ CRN ☐ Trust / Dept ☐ Other
		☐ <1 year ☐ >1 year ☐ >3 years	☐ CRN ☐ Trust / Dept ☐ Other
We have not identified specific individuals yet, but have started discussions with		☐ Trust R&D ☐ Local CRN ☐ Other _____ ☐ None	

Do you have experience within your department of electronic data entry (i.e. entering clinical or research data into an electronic case report form?)?	☐ Yes ☐ No
Does your site have electronic or paper-based medical records?	☐ Paper ☐ Electronic ☐ Both
If you use electronic records, please state the name and version of the system you are using (e.g. Auditbase, Practice Navigator, other)	
Do you have adequate storage facilities for trial documentation (e.g. either a locked office or cabinet to hold approximately 4 lever-arch files)?	☐ Yes ☐ No
Do you have archiving facilities at your Trust for trial documentation for at least 7 years?	☐ Yes ☐ No

Section 6 – Potential PI details

These questions are asked to find out who is likely to be the Principal Investigator (PI) at your site, if selected. The PI has overall responsibility at your site for the conduct of this trial, though they can delegate tasks to other trained individuals. The PI does not have to be a Head of Service, though support from the Head of Service will be needed. The PI could be an audiologist or a clinical scientist. The PI will receive training and support to carry out their roles and responsibilities, where needed.

Although previous research experience is not a requirement to be involved in the trial, we are interested in details of the potential PI's previous experience (if applicable).

Name of potential PI	
Job Title of potential PI	
Telephone number	
Email address	
Please briefly describe any previous experience of the PI in service improvement or research?	
Has the potential PI been a PI previously on a research project or trial?	☐ Yes ☐ No
If yes, what kind of projects were they a PI on? *Tick all that apply*	☐ CTIMP (drug trial) ☐ Medical device trial ☐ Complex intervention trial ☐ n/a (not been a PI before)
Does the potential PI have a current (within last 2 years) GCP certificate?	☐ Yes ☐ No

Section 7 – Declaration

Using the information provided, could your site support **all** requirements for this trial?	☐ Yes ☐ No ☐ Unsure/Would need more information
If no, please give details of the areas you are **unable** to support. *We may be able to provide solutions to some barriers.*	
Please provide any additional information you feel is relevant to support your participation in the trial	

Section 8- Questionnaire Completed by:

Name of person completion form:
Job Title:
Telephone number:
Email address: