



## Site Delegation Log STARFISH

<b>Site Name:</b>	
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<b>Principal Investigator:</b>	
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<b>A</b>	Local approval for trial	<b>H</b>	Assesses SAEs	<b>O</b>	Training of clinicians to perform intratympanic injections
<b>B</b>	Inform patient of trial	<b>I</b>	Identification of subject	<b>P</b>	Perform intratympanic injections
<b>C</b>	Obtain informed consent	<b>J</b>	Completion of CRFs and DCFs	<b>Q</b>	Perform AB words test
<b>D</b>	Confirm patient eligibility	<b>K</b>	CRFs and DCFs review and sign off	<b>R</b>	Perform pure tone audiogram (blinded assessment)
<b>E</b>	Patient registration/randomisation	<b>L</b>	Investigator Site File maintenance	<b>S</b>	Perform otoscopy
<b>F</b>	Prescribing of investigational product	<b>M</b>	Perform trial related assessments	<b>T</b>	
<b>G</b>	Report SAEs	<b>N</b>	Questionnaire administration	<b>U</b>	

**\*\* PI initials**

By initialling an entry, I confirm that the person completing the entry is authorised to perform the study procedures in the tasks section, and that the person is qualified to undertake these tasks. I also confirm that the person is appropriately informed about the study protocol and relevant study procedures

Name (please print)	Trial Role	Tasks Delegated by PI* (see legend above)	Initials	Signature	Date of signature	Date of Duties		PI initials**	Date of PI Initials
						From (DD-MMM-YYYY)	To (DD-MMM-YYYY)		



**Site Delegation Log**  
**STARFISH**


**The PI should sign below during the Site Close-Out visit**

I have reviewed the information on this log and have found it to be accurate. All delegated duties were performed with my authorization.

**PI Signature:** \_\_\_\_\_

**PI Initials:** \_\_\_\_\_

**Site close out Visit Date:** \_\_/ \_\_/ \_\_\_\_