Will participants in the study be aware of which active or comparator IMP they are taking?

Code breaks/randomisation lists to be provided to pharmacy. If using KCTU randomisation service, unblinded emails used for dispensing can be filed and used for emergency code break. The online KCTU randomisation system cannot be used for emergency code break.

**Contract to eSMS**

*Arranged via Jackie Pullen for CTIMP trials and via R&D for non-CTIMP trials*

Code break envelopes to be provided by IMP manufacturer to eSMS. Include the requirement for code break envelopes in the specification when costing the IMP

Yes

In-house provision via pharmacy if willing to provide a service

Acceptable to KHP sponsor (R&D or KHP-CTO)?

Yes

No

An immediate service is required

Are dispensing pharmacies willing to manage their own code break

Is the KHP pharmacy dispensing for all recruited participants?

No

Yes

A three hour service delay is clinically acceptable

It is 3am on Christmas morning and a physician in A&E requires code break due to accidental overdose in a toddler or they require additional information about the IMP that is not available through normal NHS arrangements due to the novel nature of the IMP.

Is immediate code break or access to information about the IMP necessary or would a delay of up to 3 hours be clinically acceptable?

No

Yes

Is it plausible that the participant or a visiting child in their home could experience overdose or side effects that may necessitate immediate code break?

Yes

**No KHP service required**

Can the IMP manufacturer / MA holder provide a service?

No

Yes

No

Yes

No

May medical, pharmacology or toxicology advice be needed out of hours due to the novel nature of the medication?