Setting-up clinical trials:

Draft guidance for Sponsors, Sites and Pharmacy Departments

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The Health Research Authority in partnership with the ECMC

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About this guidance and how to use it

The UK is improving the set-up of clinical trials at sites, to be a competitive and enabling environment for research, contributing to more research happening for the benefit, health and wealth of the UK population.

This document provides clear steps for setting up clinical trials, focusing on collaboration, communication and expectations between Sponsors, Sites, and Pharmacy teams.

It covers three key stages of identifying and setting-up sites in three colour-coded sections:

- **Assessing site feasibility** - including site identification and site selection steps
- **Planning and arranging set-up** – including confirmation of set-up through signed contract exchange
- **Site initiation** – including sponsor green light to open

This guidance is for all organisations to follow when setting up trials in the NHS. It aims to:

- simplify and standardise the set-up process
- make the information needs, decisions, commitments and actions clearer at each step, and
- remove duplication of UK trial-wide set-up activities

This document uses the term site to cover all locations undertaking relevant research delivery activities in accordance with the protocol.

All organisations are expected to follow this set-up pathway and ensure they are not duplicating the work of other organisations or repeating previous stages.

An important aspect of this guidance is clarifying what should be reviewed and considered at each stage of the set-up journey. A tiered approach to assessing information avoids internal duplication of reviewing the same considerations several times.

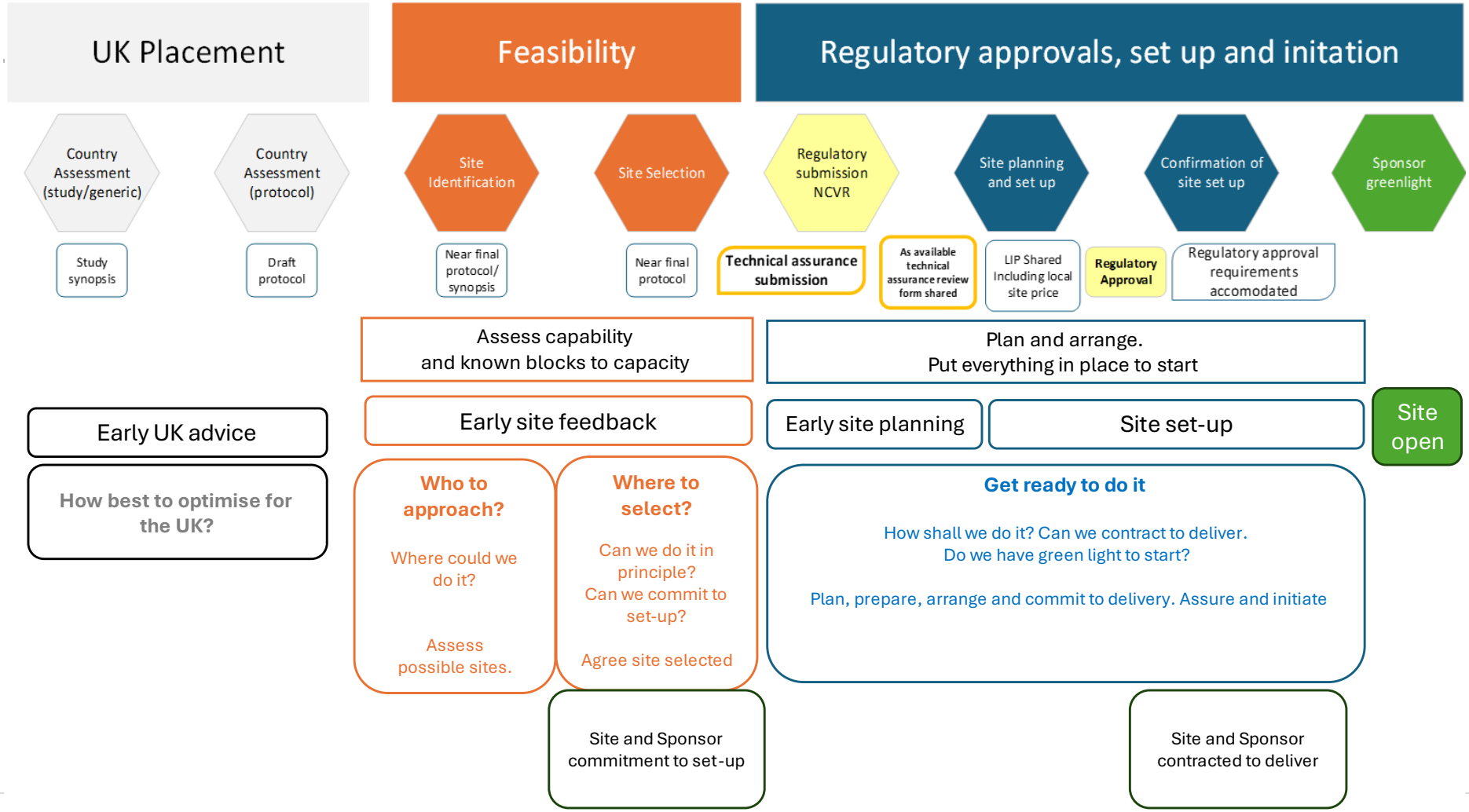
For example, at site selection only known blocks to capacity need to be considered e.g. known significant vacancies in a team, because this is the level of detail that is likely to be accurate and material at that time. Blocks are known issues that will prevent the trial proceeding based on known information. As set-up proceeds, capacity can be arranged and put in place and if more specific blocks later become known, such as competing studies that need the same specialist pharmacy expertise or equipment, they can be addressed.

This guidance focusses on sponsor-site interactions. Alongside this activity other study-level activity will take place. Specifically, Sponsors will submit for pharmacy technical assurance asking one selected site to conduct the lead pharmacy review (except for non-commercial self-managed reviews).

The lead pharmacy reviewer works with the Sponsor to complete the review and resolve any queries on behalf of other sites. The purpose of this review is to collate all the relevant information from the Sponsor to support site set-up and resolve any queries once, so that the Sponsor does not have the burden of dealing with individual and repeated queries from individual sites. If any aspects of the Lead Review are unclear to sites these should be raised with the Lead Reviewer rather than the Sponsor.

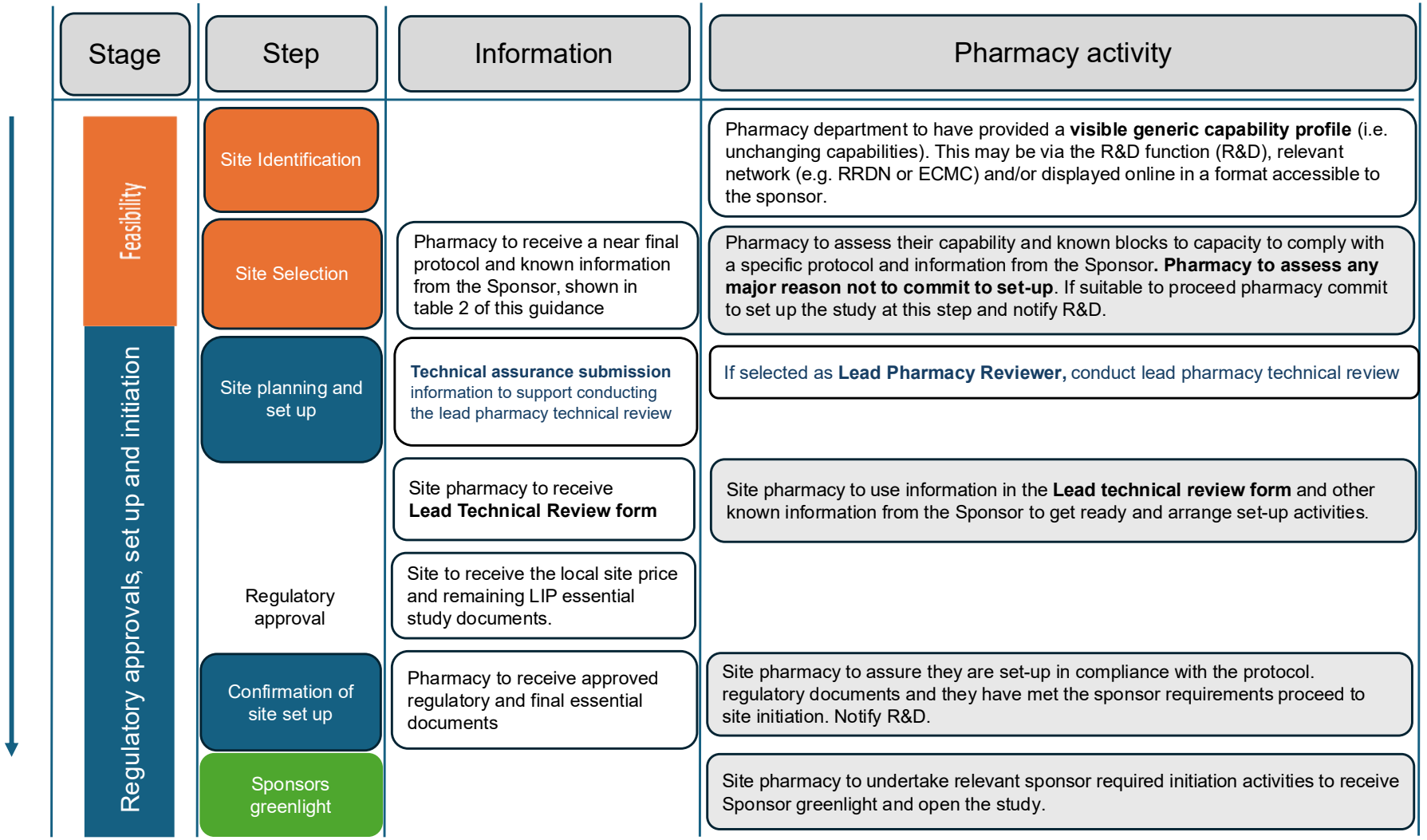
This guidance has been developed in partnership and has included Sponsors, Sites and Pharmacy R&D community. A list of organisations that have fed into this work are on the ECMC website. A summary version of this guidance and slide deck is also available.

The set-up pathway: An overview for sponsors and sites



Version 1.2. Last updated 26/05/2025.

The set-up pathway for Pharmacy



Assessing site feasibility

Introduction to site feasibility

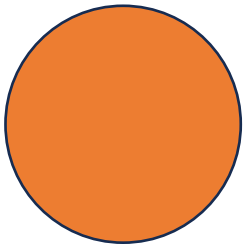
Sponsors must do everything they can to ensure the likely success of their clinical trial. This means ensuring they can recruit to time and target, always protecting the safety of participants and the integrity of data for reliable results. It also means making sure that the time and resources spent setting-up a trial is worthwhile, which is true for sponsors as well as the organisations taking part and particularly for NHS departments.

Site feasibility consists of two steps: site identification and site selection. This is a filtering process where potential sites are identified and then filtered down against protocol-specific requirements. At the end of the site feasibility process, sites that meet the requirements and agree to proceed are confirmed by the sponsor as selected sites.

Site feasibility requires accurate and comprehensive information from sponsors, and timely communication from potential sites.

Site feasibility consists of the following activities:

- **The sponsor undertakes a generic assessment** to identify sites based on a synopsis of general requirements.
- **The sponsor asks the site to provide feedback on a protocol specific assessment** based on the near final protocol and ends in a decision whether the site will be selected to set-up and take part in the trial
- **When a site or location is selected** there is an expectation and a commitment from both the Sponsor and the site to set-up.
- At this point sites taking part in commercial studies must be ready to accept the site price allocated to them later during set up via the NCVR process



Site Identification

Purpose of site identification	
Sponsor	• To find out who to approach. • To decide whether a site might be suitable to take part in principle.
Site	• To decide whether to express an interest in taking part. • To find out if a trial is possible at that site/location in principle.

Actions at site identification	
Provide information	
Sponsor	• Provide a trial outline, protocol synopsis or draft protocol • Provide known details of the trial requirements (as table 1 below)
Site	• Provide organisational details, profile and capability. • This should only be information which only changes occasionally, for example aseptic capability. This is likely to be provided to sponsors by either a coordinating function, the R&D department, local networks and / or through site ID tools (for example, RDN site ID) • For ECMC studies, site capability profile information is provided in the ECMC site feasibility tool

Conduct a generic capability and feasibility assessment

Sponsors and sites assess

- Known capability requirements and infrastructure needed.
- Interest- is there a potential principal investigator?
- General population and expertise at the site.
- Any known sponsor requirements.

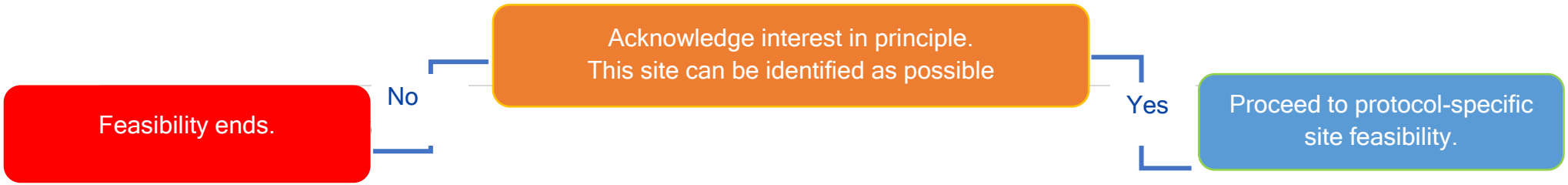
Pharmacy: At this stage of feasibility sponsors will only require generic capability information from pharmacy departments, this information is likely to be known by a coordinating function, such as R&D, or available through RDN tools and may not require any direct pharmacy input. However, it is good to establish relationships between sponsors and support departments as early as possible.

Table 1 below gives examples of the **generic pharmacy capability assessment** a trial may require at this very early stage.

Ask: could the trial be delivered at the site in theory based on known capability and infrastructure?

Table 1. Example generic pharmacy early capability assessment

Is the trial phase 1?	if yes phase 1, does the trial need a specialist unit, are we a specialist unit?
Does the trial require aseptic manipulation within pharmacy?	if yes, do we have an Aseptic unit?
Is the trial gene therapy?	if yes, do we have a license for GT? Do we need additional expertise outside of pharmacy?
Is the trial an ATMP?	if yes, do we have a license (Is aseptic manipulation required? Do we need a GMP/QP licence?) Do we have the expertise to manage an ATMP within pharmacy? Do we need assistance from other functions within the hospital?
Is the trial radio-pharmacy?	if yes, do we have a specialist site with clinical scientist or radio pharmacist?
Does the trial require routine storage of IMP outside of the pharmacy department or provision out of normal working hours?	If yes, can we comply to these requirements?
Who is responsible for oversight of IMP?	If IMP is being dispensed outside the site, who is responsible for oversight? If not the site, then pharmacy involvement and set-up role is limited



Site Selection

Purpose of site selection	
Sponsor	• To determine which sites are fundamentally capable and have likely capacity to deliver the trial in line with the protocol. • To find out who can commit to setting up the trial • To decide who to select as a site and commit to set-up
Site	• To determine whether the site is fundamentally capable of delivering the trial based on the known information in the near final protocol. • To decide whether to commit to setting up the trial

Summary of actions for site selection

- **Provide:** Near final protocol-specific information
- **Assess:** Protocol-specific feasibility
- **Ask:** Can we commit to set-up this trial based on the known protocol requirements?
- **Agree:** Site selected and commitment to set-up

Actions at site selection	
Provide information	
Sponsor	• Provide a near final protocol (and inform site of timing of when Lead Technical Review outcome and pharmacy manual are expected). Be clear with the site about any known conditions of participation, including all known timelines. • Provide any known details of information requirements shown in table 2 below
Site	• Provide details of known capability and blocks to capacity to run the trial based on the protocol provided, within expected timelines or provide timely negative response • Communicate any known fundamental conditions of participation or any issues which need resolving.
Conduct a protocol-specific, site feasibility assessment	
Sponsor and site assess: • approximate resource and IMP management requirements • any known, fundamental blocks to capacity and capability • the care pathways at site or different locations. Local hub and spoke models or home care • available expertise and the team. Any known training needs. Is there an interested Principal Investigator? • potential participant population and numbers. • interest and any likely requirements for sponsor action.	

Pharmacy: At this stage of feasibility sponsors will require protocol specific information from pharmacy departments, this information will require direct pharmacy input. The information the sponsor provides should allow the site pharmacy department to decide if they are able to comply with the protocol in principle and there are no known significant capacity blocks, so that the site can commit to selection and set-up. At this point it is expected that reasons not to commit to set-up will be known fundamental blocks

Table 2 below gives **examples** of the **pharmacy protocol-specific feasibility assessment**. This is a guide and should not be taken as absolute information required or prevent information sharing. At this early stage, sites and sponsors should provide any known information to help each other decide whether to commit to setting-up the site. Not everything can be known at this step and changes will occur, but these changes can usually be accommodated during set-up.

Ask: Can we commit to set-up this trial based on the known protocol requirements?
Are there any known, fundamental reasons why we cannot commit to set-up?

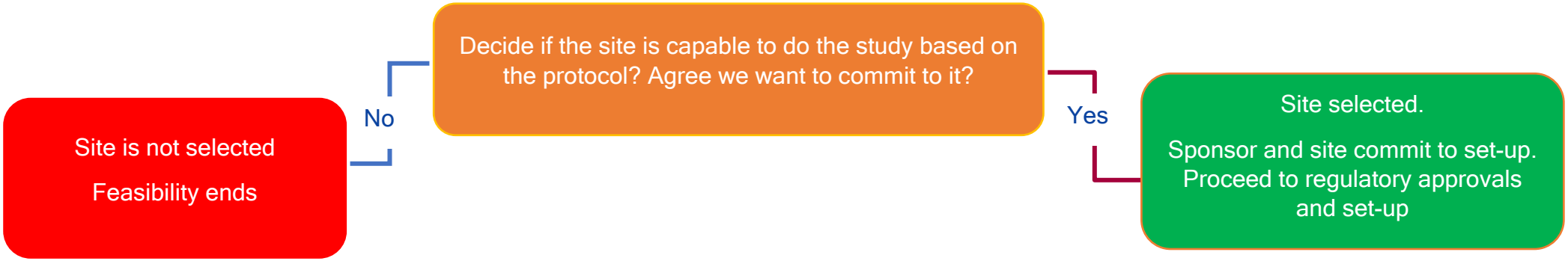
Table 2: Example pharmacy protocol-specific site feasibility assessment for selection

Pharmacy assessment	Sponsor	Pharmacy
Assess any known blocks to capacity When is it likely?	• **Provide** proposed dates when aiming to start at the site. If the site is unable to commit to the timeframe, inform them of any flexibility around this i.e. can they open earlier or later than the proposed dates. • **Review** information of any studies the site informs you they already have open/committed to open which may be a competing trial and decide whether they are acceptable to run alongside.	• **Decide** whether you are likely to have capacity to undertake this trial within the proposed timeframes? • **Consider** anything else on the horizon which may prevent you being able to take part. • If you are unable to commit to the proposed timeframe, **inform** the sponsor if you could do it within a different timeframe e.g. "we would be unable to open in June due to other open studies, but we could open in September, would this work for you?" • **Inform** the sponsor of any studies you already have open/are committed to open which may compete with the proposed trial or required resource e.g. aseptic unit/gene therapy suite etc
Assess specialism, licenses and numbers required.	• **Inform** the site of how many (a range) of participants they would be expected to recruit? • Any required licencing information e.g. what licences are required.	• Consider whether capacity exists to support intended dosing schedule (e.g. weekends, 24/7 recruitment expectations etc) • **Confirm** all licenses are in place

Assess approximate resources and essential IMP management requirements	**Provide** information on essential IMP management requirements, equipment, expertise and approximate resources needed to help the site decide if they are likely to be able to comply with the protocol. Including details on: • **IMP** - is there anything unusual about the drug/drug regime? • **Stability requirements of the IMP**- If less than 4 hours can this be safely delivered at bedside? If the IMP needs to be made up at the bedside – what are the potential hazards? Or is it required to be made up in pharmacy? • **Any specific transport requirements** if preparation location is different to the participant location. For example, some organisations prepare drugs at one hospital site and transport to different hospital sites across the local area. • or in surgery, can the ward staff or surgeons administer it? • **Any known staff requirements:** For example, if IMP is to be given on the ward • **If preparation/ administration** is to be performed by unblinded/blinded staff, what will this require?	**Decide and confirm:** • you could safely manage the type of IMP detailed by the sponsor. • you could safely manage the stability requirements of the IMP detailed by the sponsor. • PI and pharmacy could safely manage any dose escalation(s) detailed by the sponsor. • you have likely capability to comply with any known blinding requirements. • if supply is from own source that this would be possible. • any specific storage requirements could be put in place e.g. -80 freezer • you could comply with any specified aseptic preparation requirements. • you could comply with the accountability requirements. • you could comply with any known details of specific equipment or resources. • if pharmacy will be responsible for IMP dispensed or administered elsewhere, can you (and relevant departments, where relevant) comply with protocol requirements.

	• **Any dose escalations**? Details of any dose safety issues. • **IMP supply source**. Details of any known or likely challenge with supply logistics e.g. batch size? • **IMP Aseptic preparation** • **IMP storage requirements** e.g. ambient, fridge, freezer. • What **accountability** is required. • any **known specific equipment** resources or information. • Any **known compatibility issues** with bags, syringes, cleaning products etc. • any **out of hours requirements** i.e. define the hours. • any **home care or outside pharmacy requirements.**	• **Assess and provide** to the Sponsor anything you already know you would need to run the trial.

Pharmacy confirms to site R&D Coordinating function if pharmacy has capability to do the trial (pharmacy are happy to be selected as a site).



Planning and Arranging Set-up

Introduction to planning and arranging set-up

Once a site is selected then the sponsor and site should work closely together to set-up the processes required for the safe and efficient conduct of the trial ensuring that any additional information requests or identified issues are managed effectively.

This step is an arranging step to get ready for the site to open. As such, feasibility assessments should not be occurring once site selection has been agreed, accepting site prices, working through and accommodating any previously unknown site issues or trial requirements during this phase. Any major blocks to taking part should have been identified at site selection but if things change afterwards for any reason, this should be clearly communicated. Any changes required to set-up as agreed at site selection (e.g. expected timelines and targets or requirements from the sponsor) should be discussed and solutions found wherever possible.

The planning and set-up stage is facilitated early on by the Lead Pharmacy Technical Review followed by regulatory approvals, National Contract Value Review (NCVR for commercial research), and all final essential documents. Site initiation requirements are agreed at this step and any visits arranged. Pre-screening should start so that participants are

This stage is complete when everything is in place to open at the site, except for those activities previously agreed with the Sponsor that occur after contract exchange (at site initiation, for example IMP delivery). Both Sponsor and site confirm set-up and a commitment to delivery by exchanging signed agreements (UK, unmodifiable).

- The **site set-up** stage is for all the activities needed to get ready to open and deliver the trial. It is not a feasibility step.
- During site set-up there is a **commitment to set-up** and any details or changes that might come after the selection step should be accommodated most of the time. Changes made by sponsors should be kept to a minimum and notification of any changes should be provided as soon as possible.
- **A site is set-up** when everything is in place that is needed at that site to be able to open, except for activities required by the Sponsor at site initiation (after confirmation of set-up and signed contract exchange).
- **Set-up is confirmed** by an exchange of signed contracts contractually confirming a commitment to deliver the trial
- The site is not open until the Sponsor confirms green light (see next section)

Site Delivery Planning and Set-up

Purpose of site planning and set-up	
Sponsors	• To help the site to plan and arrange resources to be ready to deliver the trial. Providing any necessary support to set-up and minimising any potential changes. • To have everything in place at site, within the agreed timelines, before initiating the trial.
Site	• To put in place a plan and arrange the resources to be ready to deliver the trial. • To have everything in place at site, ready to initiate the trial within the agreed timelines.

Summary of site planning and set-up

- **Provide:** Technical review forms. Local information pack, initial assessment letter, local site prices and relevant contracts. Regulatory approvals and manuals when they are available.
- **Ask:** How shall we do it at site to comply with the protocol? What do we need to put in place now to be ready to initiate?
- **Arrange:** Resources, oversight arrangements and activities needed to open the trial at site.
- **Confirm:** Site is set-up to commit to delivery, to proceed to contract exchange and site initiation.

<table>
<tr><th colspan="2">Actions at site planning and set up</th></tr>
<tr><td colspan="2">Provide Information</td></tr>
<tr><td>Sponsor</td><td>• Completed Lead Pharmacy Technical Review sent to R&D (as soon as available) who should pass it on to pharmacy immediately
• Local information pack and Initial Assessment Letter, NCVR-derived local site prices and model contracts
• Regulatory approvals and pharmacy manual (as soon as available)
• Communicate any changes required following regulatory approval
• Communicate any new delivery partner/vendor and technical information with site.
• Communicate any unforeseen changes or delays
• Communicate any upcoming changes e.g. changes to vendor or technical information</td></tr>
<tr><td>Site</td><td>• Communicate (between R&D and Pharmacy) receipt of lead pharmacy technical review
• Communicate progress to the Sponsor
• Communicate any unforeseen changes or delays</td></tr>
<tr><td colspan="2">Plan and arrange resources, set-up.</td></tr>
<tr><td colspan="2">Sponsor and site:
Arrange and set up how we will do it. Start pre-screening where possible. Agree requirements for site initiation
- Methods needed to deliver all the trial requirements
- Oversight arrangements for delivery locations or partners
- Site price incorporated into the contract and agreement localised.
- Agreements with partners and HR contracts
- Staff in place
- Training
- Resources, IT and equipment
- Essential documents in place
- Documents localised as required</td></tr>
</table>

Pharmacy: At this stage sponsors will provide the Lead Pharmacy Technical Review to the site pharmacy team as soon as it is available, via the site R&D coordinating function (R&D should pass this on to pharmacy). This information should allow pharmacy to plan, prioritise actions and start to put resources in place to deliver the trial, particularly where studies might be complicated. Regulatory approval and all approved essential documents are then provided by the Sponsor for the site to confirm compliance and final set-up. Some set-up activity may need to happen after signed contract exchange and confirmation of set up for example, the IMP may not yet be on site. However, during this step the site should plan to be ready to receive the IMP from the sponsor after the sponsor's greenlight and to carry out any activity required on receipt. All site initiation or post contract set-up activities must be agreed with the sponsor.

Table 3 below sets out **examples of planning and set-up activity** which may be required during this stage. The sponsor should include the below information in their technical review submission to enable it to be captured by the lead reviewer and used by all sites. Once the regulatory approved documents are available these should be shared with pharmacy for assurance and final set up.

Ask: How shall we do it at site to comply with the protocol?
What do we need to put in place now to be ready to initiate?
What activities need to be established to facilitate the conduct of the trial and provision of the IMP at our site?

Table 3 Examples of planning and set-up activity to be arranged

Pharmacy arrangements	Sponsor/Technical Review Form	Pharmacy
Set up and put in place how we will do it:	**Provide and arrange:** • Final document set including any pharmacy-specific documentation • **Supply:** delivery details/requirements to the site. (if supplying the IMP) • **Labels:** labelling details and requirements. • **Assembly** and reconstitution **Randomisation and blinding** information requirements including the process for **emergency Unblinding:** who is responsible for both randomisation and unblinding. How will this information be communicated to pharmacy? • **Systems and log-ins.** ensure the site has access to any required systems, the appropriate user type and access permissions and the appropriate number of log ins. • **IMP/NIMP requirements.** - any IMP temperature requirements.	**Arrange:** • **Supply:** If you will be using local supply of the IMP ensure arrangements for this are in place to begin dispensing when required. If the sponsor is providing the IMP supply, ensure the sponsor is aware of the organisation delivery address and any local delivery requirements e.g. deliver to pharmacy loading bay. • **Digital systems:** Load/create label into local system. Load into prescribing systems, aseptic unit production system etc. • **Dispensing procedures**: Use the following information to form local working/dispensing instructions: - assembly and reconstitution method(s) any randomisation and blinding instructions (including emergency unblinding process) including internal contacts and processes

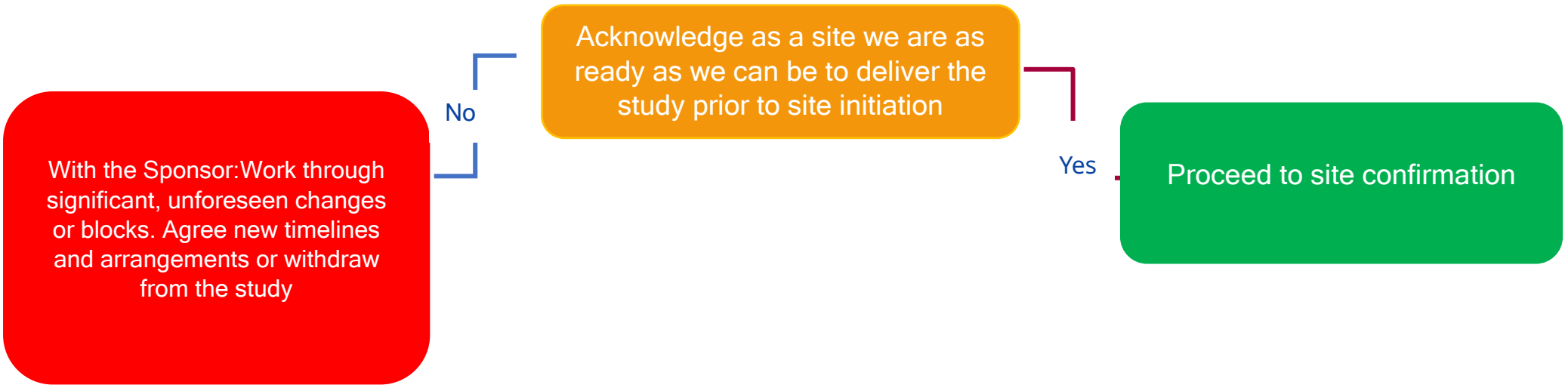
Pharmacy arrangements	Sponsor/Technical Review Form	Pharmacy
	- any IMP storage requirements - any prescription requirements. - any dose calculations and any required methods for these. - any requirements for drug transportation e.g. temperature control whilst delivering IMP to another location e.g. ward. - accountability logs - IMP retention requirements (e.g. for monitoring) - reimbursement of medication if not supplied • **IMP delivery information including:** - number of containers to be delivered - ordering information - shipping and delivery information - receipt information - return/destruction methods	- any oversight requirements of IMP storage. - requirements for ordering, delivery and return/destruction of IMP. - Use of provided E-Systems e.g. IRT - dispensing procedure information - dose calculation methods and associated checks (if required) - dose escalation and de-escalation requirements and how communicated - what clinical checks required - requirements for drug transportation • **Randomisation and blinding:** ensure the appropriate pharmacy staff have access to any required systems and have completed any relevant system training. Complete the delegation log to reflect. • Review of blinding controls and blind/unblind communication channels. May include assessment of local risk

Pharmacy arrangements	Sponsor/Technical Review Form	Pharmacy
		associated with provision of IMP and labelling, and blinding processes • **Storage/facilities and oversight**: ensure the appropriate storage/facilities are ready - if storing outside of pharmacy e.g., on the ward, A&E or theatres, visit the area, check the storage (ensure safe and secure storage, temperature control and appropriate accountability measures in place), and discuss the requirements with local staff trial team and Principal Investigator. Train of delegated staff - set-up a mechanism for oversight - agree expectations if IMP not retained by pharmacy including ability to remove permission for external storage of IMP. - ensure the relevant temperature controls are in place e.g. visit the storage and

Pharmacy arrangements	Sponsor/Technical Review Form	Pharmacy
		check the temperature and the thermometer and discuss the control arrangements with relevant staff. - arrange for any required calibration of thermometers. • **Prescription build:** Use the prescription information to build prescription into local system. • **Chemotherapy build**
Training and essential documents	**Provide:** • **Site training:** Arrange required site training with site. • **Pharmacy site file:** provide all essential documents **Documents for localisation**: • provide any word versions of any documents which require localising. • work with pharmacy if local system/processes are to be used e.g. internal documents or systems	• **Provide and arrange** availability for any site training. • **Receive or put together** the pharmacy site file with the sponsor provided documents. • **Localise** any documents as required.
Requirements for site initiation	• **Provide and agree** with the site any set-up activities to happen	• **Agree** with the Sponsor activity to happen following contract exchange.

Pharmacy arrangements	Sponsor/Technical Review Form	Pharmacy
	after contract exchange (e.g. supply of IMP) • **Agree** site initiation date with site.	• **Agree** site initiation date with sponsor.

Pharmacy confirms to site R&D Coordinating function; pharmacy is set-up and ready to deliver and open the trial prior to site initiation (e.g. all is in place except for agreed IMP delivery).



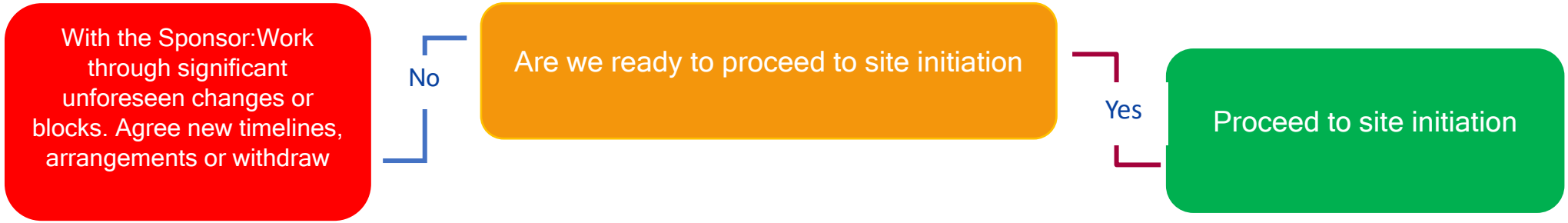
Confirmation of Site Set-up

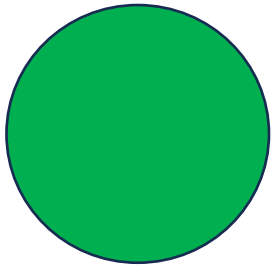
Purpose of site confirmation	
Sponsor	• To confirm all resources are in place and the site is set-up in compliance with the protocol and regulatory documents. • To confirm the site is ready to open except for activities required by the Sponsor to occur at site initiation. • To confirm contractual responsibilities and agreement to deliver
Site	• To confirm to the Sponsor all local resources are in place and the site is set-up in compliance with the protocol and regulatory documents. • To confirm the site is ready to open except for activities required by the Sponsor to occur at site initiation. • To confirm contractual responsibilities and agreement to deliver

Summary of actions at site confirmation
• Ask: Are we ready to start site initiation? • Conduct: contract execution and exchange • Provide: Signed contracts. • Confirm: resources in line with plan and initiation requirements by authorising contract signature.

Actions at confirmation stage	
Provide	
Sponsor	Appropriate sponsor representative to sign and exchange the contract.
Site	Appropriate site representative to sign and exchange the contract.
Confirm set-up prior to site initiation	
Sponsor and site confirm by exchanging signed contracts: • How the site will deliver the trial • Who at site will deliver the trial • When the site will deliver the trial (time) • Recruitment numbers (target) • Responsibilities of site to deliver the trial and the relationships with the sponsors and any delivery partners.	

Pharmacy: At this stage pharmacy should have already confirmed to the Sponsor and to the site R&D Coordinating function they are set-up and ready, except for any actions previously agreed with the sponsor to occur at site initiation. R&D will confirm the site is set-up via exchange of signed contracts with the sponsor once all of the site is ready to initiate.





Site Initiation

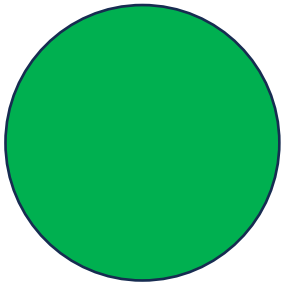
Introduction to site initiation

Through the exchange of signed contracts both parties have committed to the delivery of the trial at the site.

At this stage sites are initiated in line with the sponsor's greenlight requirements. Any activity the sponsor has agreed should take place after contract execution can now occur. For example, IMP delivery may occur at this stage.

This stage is complete when all site initiation activity has been completed, and the sponsor has provided the site with the greenlight to open.

- The **site initiation** stage is for all the activities needed to comply with the sponsor greenlight requirements. This includes the sponsor providing any outstanding training and essential documents.
- At this stage the site is already committed to delivering the trial.
- **A site is initiated** once all the initiation activities have been completed as per the sponsor greenlight requirements.
- **Site initiation i**s confirmed once the sponsor confirms their **greenlight** that the site is open.



Sponsor Greenlight

Purpose of site initiation and sponsor green light	
Sponsor	• To put in place any activities that have been agreed can only happen after contract exchange (e.g. IMP delivery) • To confirm Sponsor is satisfied everything is in place to comply with the protocol and open the trial
Site	• To put in place any Sponsor agreed activities that can only happen after contract exchange (e.g. IMP delivery) • To confirm Sponsor has formally given their green light that everything is in place to comply with the protocol and the trial can open

Summary of site initiation and activities

- **Conduct:** site initiation tasks e.g. site initiation visit.
- **Provide:** All resources, training and essential documents needed as agreed with the sponsor
- **Ask:** Do we have everything in place to open? Do we have green light from the sponsor?
- **Confirm:** Everything is in place to open and comply with the protocol Sponsor green light has been issued.

Actions at site initiation stage	
Provide	
Sponsor	• Any resources or information as agreed for example: IMP, training to site. • Confirmation of regulatory green light
Site	• Availability for site initiation visit • Confirmation everything is ready at site to open to comply with the protocol
Complete site initiation	
Sponsor and site arrange and conduct • Site initiation visit, as appropriate • Relevant supplies provided to site e.g. drug, devices, equipment etc have been shipped or arrived as appropriate. • Any other agreed initiation requirements	

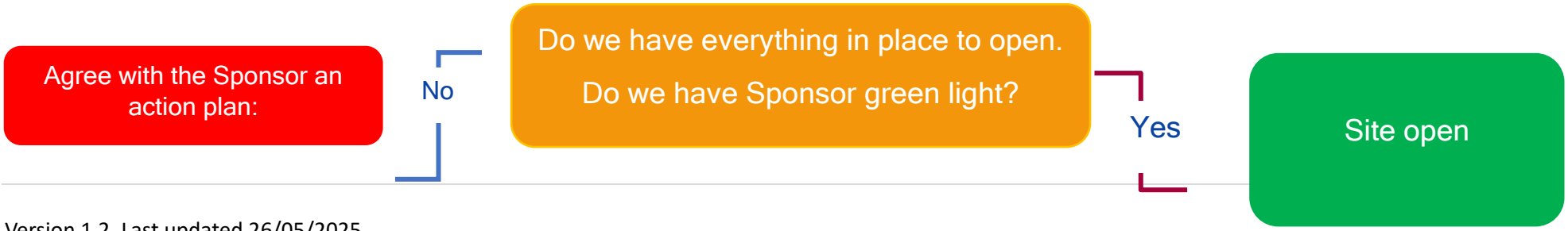
Pharmacy: At this stage pharmacy should undertake any **site initiation** activity as per the sponsor requirements. Examples of these are given in **table 4**

Ask: Do we have everything in place to open and comply with the protocol?
Do we have green light from the Sponsor?'

Table 4: Examples of pharmacy site initiation activities

Pharmacy initiation	Sponsor	Pharmacy
Final set-up and compliance	• Undertake any relevant training with the site. • Ensure shipment of any required IMP, devices and equipment. • Hold site visit (if required). Check set-up and compliance. • provide QP certification for each IMP batch / or assurance statement that all IMP supplied for the trial will be fully QP released • Confirm Sponsor green light	• Arrange for the relevant staff to undertake any sponsor required training. • Hold required site initiation visit and ensure the relevant staff are available. • Receive IMP and any relevant equipment and ensure any relevant activity is completed e.g. stored in the relevant area ready for dispensing. • Activate trial within internal systems/processes e.g. regimens available for selection within electronic systems, pharmacy staff notified of trial go-live etc

Pharmacy confirms to site R&D Coordinating function everything is in place



Future proposals for pharmacy guidance

This guidance is draft for use in a pilot phase. It will be updated and improved based upon feedback from sites, sponsors and pharmacy teams.

To take part, feed into the pilot and comment on this guidance please email: pilot.testing@hra.nhs.uk and ecmcadmin@cancer.org.uk referencing pharmacy assurance pilot.

The HRA and UK Clinical Research Delivery (UKCRD) programme is considering further activities to provide clarity and consistency in processes and to reduce duplication. The potential for a lead reviewer to prepare dispensing information once, for other pharmacists to use may be explored.

In the future Sites and Sponsors may document the information to be agreed at site selection in a site selection intention letter.

We may explore improved compatibility between lead technical review and NCVR as exists in Scotland

Thank you