Steps for setting up a registry based trial

Setting up a registry based trial follows the same Clinical Trial Life Cycle as other trials, but there are some aspects that are specific to registry trials:

Registry Trial type	Registry Design: from Concept to Data Storage	Registry-Randomised Controlled Trials (rRCT)	
Purpose		Adding a trial to a pre-existing registry	Developing a registry in conjunction with a trial
Planning	**Concept** You should have a particular cohort and outcome type in mind you want your registry to capture. E.g. survival outcomes or quality of care received by those diagnosed with a particular condition.	**Study Question** Where an existing clinical registry will be used, consider whether the registry is already designed to capture the patient population necessary for the conduct of the r-RCT.	**Study Question** Where a pre-existing registry will NOT be used, consider whether a clinical registry can be designed and implemented in a timely and cost-effective manner to capture the data necessary for the trial.
Development	**Registry Protocol Development** The aims, objectives and scope of the registry need to be clearly defined in a protocol.	**Trial Protocol Development** The trial, even when run through a registry, will need a standalone protocol, like other trials.	**Trial and Registry Protocol Development** Trial and Registry Protocol Development The trial will need a standalone protocol, like other trials. In most cases, the registry may also need a standalone protocol, particularly if intended for use in future trials.
Ethics Approval	The protocol needs to be submitted to an ethics committee for review. This ethics committee may provide overarching ethics approval for all sites where the registry will be implemented or may be specific to one or a handful of sites.	Just like other trials, an r-RCT will be required to go through an ethics approval process that is separate to the registry ethics approval.	The protocol for both the trial and the registry needs to be submitted to an ethics committee for review.
Database Design	The software and data points that will be captured need to be decided upon. You may decide that certain questions are mandatory.	Often, the registry will not include all data points necessary for the conduct of the trial. In this case, mechanisms for capturing that additional data (such as date of consent) will need to be arranged. Mechanisms for capturing data for patients at sites not involved in the registry need to be put in place.	One of the biggest advantages of designing a registry and trial in tandem is that the registry database can be custom-built to capture all necessary data points for the trial. This avoids the requirement for additional data collection outside of the registry data fields.
Site Registration	You will need to decide at which sites or institutions your registry will be implemented.	You will need to decide at which sites or institutions your trial will be implemented. You may have decided to only open the trial at sites that are already involved or in the registry or you may have chosen to involve a mix of registry sites and sites that are not involved in the registry.	Another advantage of building a trial and registry in tandem is that all sites can be involved in both the trial and registry, avoiding the need for separate processes for non-registry sites.
Governance	Each site that agrees to be involved in the registry will need to formalise involvement through the research governance office (RGO), which is responsible for the functioning of that site.	Each site that agrees to be involved in the trial will need to formalise involvement through their research governance office (RGO), which is responsible for the functioning of that site.	Each site that agrees to be involved in the registry and the trial will need to formalise involvement through their research governance office (RGO), which is responsible for the functioning of that site.
Patient Enrolment	There needs to be a systematic process for identifying patients for inclusion in the registry. Examples include via review of multi-disciplinary meetings or pathology reports to capture all relevant patients.	Patients will need to be identified and consented for the r-RCT. They may include identification through their pre-existing involvement in the registry if recruitment via this avenue has been approved.	Patients will need to be identified and consented for the r-RCT. This is likely to be through usual mechanisms for trial recruitment.
Data Capture	Data required for the registry will need to be accessed and stored by delegated project officers.	Study coordinators will need to be appointed at each site, with clear demarcation of trial responsibilities from pre-existing registry data collection processes.	Study coordinators will need to be appointed at each site who will assist in study and/or registry implementation. Plans for registry maintenance upon completion of the trial need to be considered.
Data Use	**Centralised Data Storage** There will need to be a secure way to share and store de-identified data centrally. One such platform facilitating this is BioGrid.	**Data Analysis** Study data will be extracted from the registry for all r-RCT patients (and combined with data for any trial patients who are not part of the registry) for analysis.	**Data Analysis** Study data will be extracted from the registry for all r-RCT patients for analysis.
Reporting		The usual mechanisms for reporting trial outcomes through presentation at scientific meetings or publication are utilised.	

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