

Developing a business case: the Hub development process

Hub Playbook Module 2

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Purpose

The purpose of this module is to help aspiring Hubs navigate the design stage of the Hub development process, from identifying the need for a Hub to developing a successful business case and delivery plan.

Summary

This module provides an overview of the six stage development process for establishing a Health Data Research Hub, from concept to steady-state delivery. It focuses on the three stages from concept development to formal assessment of a business case or funding application, describing the points during the process at which a candidate Hub will be assessed by HDR UK and its funding partners, and the criteria that a proposal needs to meet to proceed.

The module also describes how HDR UK will work with you. Our ethos is to work together at pace. We will manage the process with you to reach key decision points quickly, eliminating ideas that won't work and focussing energy on building an effective plan. To support your planning, this module sets out the key components of a Hub delivery plan, provides tools to get you started, and refers you to more detailed guidance on each topic. And it discusses how the process for establishing a new Hub may vary, depending on what infrastructure and funding is already in place and on whether the need has been identified by a funding body, a group of potential data users, or data owners.

Learning objectives

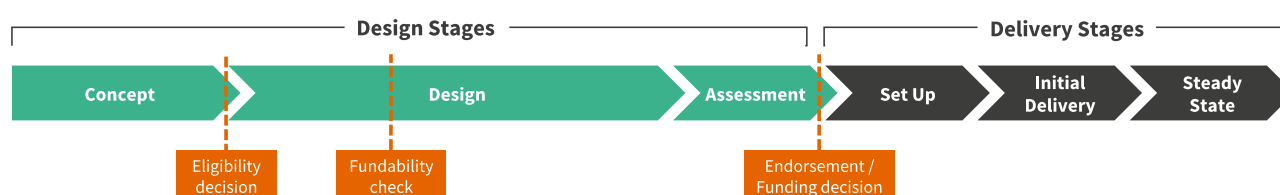
When you have read this module you will:

- Be able to describe the six phase of the Hub development process
- Understand the evidence you will need to gather to validate your Hub concept
- Understand the core requirements for producing a delivery plan and business case
- Understand what the key decision points are in the process, and how decisions are made
- Understand how the process may vary depending on whether or not new funding is required, and the scale and source of funding

1. The six stage Hub development process

The core Hub development process has six stages, starting with the initial concept, and ending with the sustainable delivery of Hub services. This module focuses on the design stages, from initial concept, through design, to assessment of a business case or funding application by a sponsor.

Figure 1. The six stage Hub development process



1.1 Working with HDR UK

The Hub team at HDR UK is here to work with you from the earliest point in your journey, through to supporting the set-up and delivery of your Hub. Our ethos is to work together at pace. From the point you contact us we will manage the process with you to reach key decision points quickly, eliminating ideas that won't work and focussing energy on building effective Hub services as quickly as possible.

Your experience of working with HDR UK through the development process will vary depending on your circumstances.

If you are considering applying for funding in response to a call for proposals from an HDR UK funding partner, the design process will be rapid. Here, HDR UK will have worked with the funder to develop the Hub concept and convene the community to discuss the call. There will be specific guidance available setting out the funder's requirements and you will have a short period of time to design your Hub and submit an application to a set deadline.

An increasing number of potential Hubs are beginning to develop their business case based on need before a funding source is identified. Others may have existing funding in place that has allowed them to establish a health data resource that they now wish to align with HDR UK's health data framework. This provides an opportunity for early engagement and iteration with HDR UK in the concept and design stages – but the support that we provide to you will still be geared to helping you progress quickly.

1.2 Key decision points in the development process

There are three “stage gates” in the design stages where HDR UK and its funding partners will assess progress and decide whether a candidate Hub should progress to the next stage of development. The purpose and criteria for the stage gates are described in the following sections.

2. Stage One: Concept

Table 1 sets out the key questions that need to be addressed to put your concept in writing, and which will guide HDR UK's evaluation of whether or not your proposal fits the Hub model and is eligible to proceed to the design stage. You will need to demonstrate a sound, service-focused concept, with realistic use cases and data sources. Answering these questions will also help you understand more quickly whether the Hub model is right for you or whether another funding source matches your need better.

HDR UK provides a concept outline template that we ask you to follow to share your thinking with us. This will help us have the right conversations with you and our partners from the outset.

Resource: [Concept outline template](#)

Table 1. Key questions for progress from Concept to Design stage

Question	Detail	Key to approval?
What is the overall purpose of the Hub?	What health areas would it serve and why is it needed?	Yes
What are the research questions and use-cases that the Hub will support?	Includes both specific known research questions and situations in which data could potentially be used to improve healthcare	Yes
What datasets would support the work of the Hub?	Are the relevant custodians engaged? Are they expected to be members of the consortium?	Yes
What is the ongoing demand for Hub data and services, beyond currently identified users?	Can you identify a continuing need for the service that justifies initial investment?	Yes
Who are the key stakeholders you expect to need to involve in your consortium	Have relationships and expectations been established with individuals and organisations?	No
What is expected from the leadership of the Hub?	Have you begun to identify the leaders you need	No
What involvement and engagement of patients and the public has taken place so far in relation to the approach?	Has patient and public involvement informed the purpose and use-cases?	No
What is your initial assessment of cost?		No
Have you identified specific commercial and non-commercial income streams		No

HDR UK can help you work through the concept stage and has insight into planned activities that may affect your work, so please contact us as soon as you feel it would be helpful. We would encourage you to start exploratory conversations with your network and host institution early. We have found that the following “conversation starters” help focus early thinking.

Table 2. Key questions for your Host Institution and network

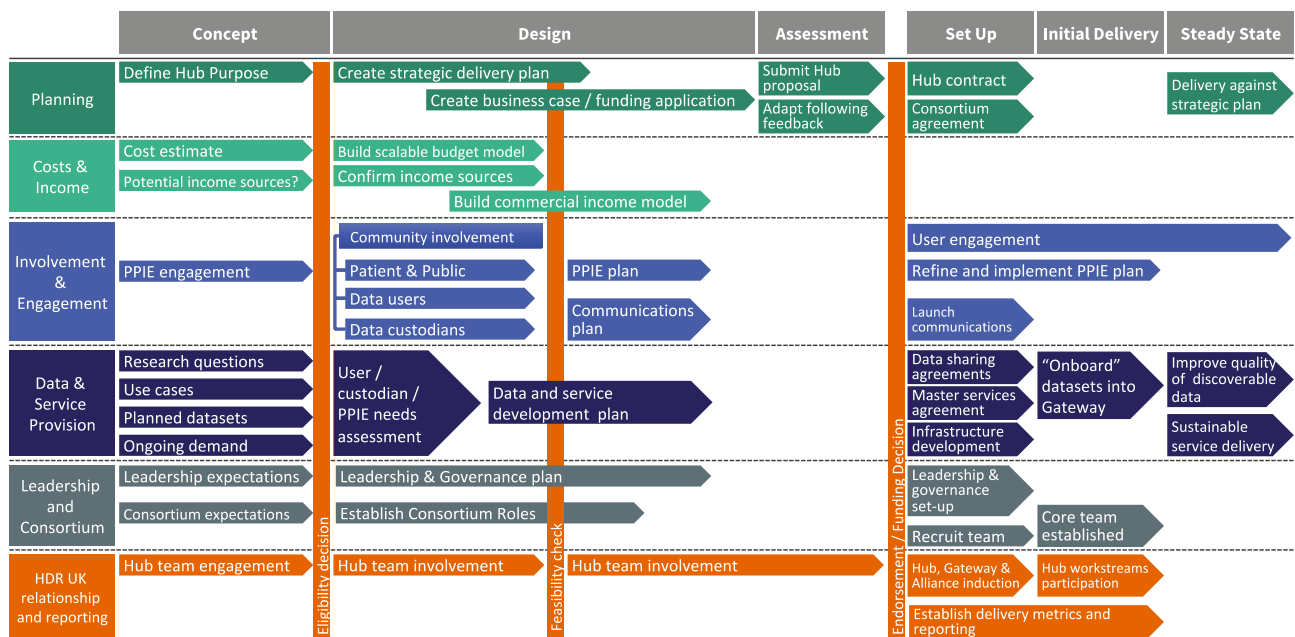
Question	Detail
Is a Hub what you and your network needs most? Module: What is a Hub?	Is your primary goal to develop a health data service for others, or are you driven by a specific research goal that requires funding? If both, can you commit fully to delivering a Hub service.
Is a new Hub necessary or could existing health data resources be used or improved to meet the need?	Your planning should include, but not be limited to considering existing Hubs, and other datasets available through the HDR Innovation Gateway .
Is your host institution willing to meet the commitments of hosting a Hub?	Will they provide active support, including financial or in-kind support?

3. Stage Two: Design

This is the point where you will need to begin the development of a formal delivery plan that you will use throughout the design and delivery stages of the Hub development process. Your delivery plan will help you gather all the information that you need to prepare either a formal business case for endorsement by HDR UK, or a grant application.

This section sets out the workstream structure and tools that HDR UK recommend that you adopt as you develop your delivery plan. We have used this structure to shape the Hub playbook, and this section provides links to playbook modules that address each workstream. The workstreams and key tasks are summarised in Figure 2.

Figure 2. Hub development delivery plan outline: workstreams and key tasks



3.1 Planning

In the design phase your planning activity needs to focus on project management, creating of a delivery plan and preparation of a business case or funding application.

Resource: Delivery plan outline

HDR UK and funders consider the number and value of a Hub's outputs, rather than their cost, to assess their importance. Delivery, on time and on budget, is necessary to retain Hub status, so it is important to build a business plan that you are confident will deliver, with an understanding of how it can evolve over time, grounded in strong initial delivery.

3.2 Costs and income

You will need to:

- Define the operational cost of running your Hub and build a scalable budget
Module: Operation costs of a Hub
- Identify potential income sources and confirm in principle "fundability" – i.e. the existence of a funder or funders willing to consider an application for support.
Module: Identifying and securing funding
- Build a commercial model for generating income for Hub services to achieve financial self-sustainability
Module: Developing a fair-value commercial model

3.3 Involvement and engagement

You will need to:

- Include patient and public involvement in the development of your plans, and develop a PPIE plan
Module: Developing PPIE - from early planning to delivery
- Involve data users and owners in the development of your plans
Module: Engagement and involvement of users and data owners
- Develop a communications plan
Module: Communications, branding and positioning

3.4 Data and service provision

You will need to conduct a needs assessment for service users and data custodians and:

- Write a data and service development plan
Module: Data management and improving usefulness
- Write an information governance plan
Module: Information governance approaches

3.5 Leadership and consortium

You will need to do:

- Identifying and secure your non-commercial and commercial consortium partners
Module: Identifying and securing partners
- Define decision making structures, ways of working and governance arrangements
Module: Consortium models - decision-making structures, ways of working and governance

- Identify the leadership and staffing resource you need
Module: Leadership and staffing

3.6 HDR UK relationship and reporting

To ensure you are ready begin the Hub set-up phase efficiently, you will need to:

- Ensure you understand the Hub review milestones and reporting requirements.
Module: Executing a legal agreement with HDRUK and meeting reporting requirements
- Ensure you understand requirements for linking with other Hubs and participating in the Health Data Research Alliance
Module: Linking with other Hubs on projects and cross-cutting work

4. Stage Three: Assessment

The nature of the assessment process for your Hub will depend on you funding requirement.

Where you have already secured the income you require to fund the Hub, the assessment will be limited to an endorsement review conducted by an HDR UK panel. The assessment will focus on ensuring that the Hub can meet the requirements for membership of the Health Data Research Hub network, and pay the HDR UK service charge.

Where additional funding is required to establish the Hub, the assessment process will depend on the requirements of the sponsor. For a research funding body this will normally involve a competitive application process, which HDR UK will participate in as a partner to the sponsor.

5. Resources

The following resources have been referenced in this module. This list excluded references to other modules in the Hub playbook.

Resource: Concept outline template

Resource: Delivery plan outline