

Step-by-Step Guide:

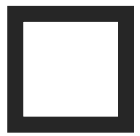
Conducting a HealthTech Pilot Study in NHS Primary Care.



Medical
Consulting
Group. —

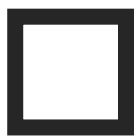


Step 1: Define the Problem and Develop a Value Proposition.



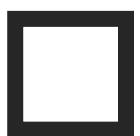
Identify Clinical Need:

Engage with primary care professionals to pinpoint specific challenges or inefficiencies in current practices.



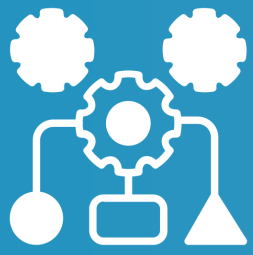
Develop Value Proposition:

Clearly articulate how your HealthTech solution addresses the identified need, outlining expected benefits such as improved patient outcomes, cost savings, or workflow efficiencies.

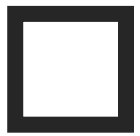


Map Current Pathways:

Understand existing care pathways to determine where and how your technology integrates.

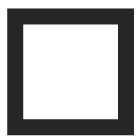


Step 2: Classify Your HealthTech Product



Determine Device Classification:

Assess whether your product qualifies as a medical device under UK regulations, considering its intended purpose and functionality.



Regulatory Compliance:

If classified as a medical device, ensure compliance with the UK Medical Device Regulations, including obtaining UKCA marking and registering with the Medicines and Healthcare products Regulatory Agency (MHRA).

(You can inform the MHRA that you are running an investigative study on a medical device here: <https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device>)



Step 3: Engage Stakeholders and Build Partnerships



Identify Key Stakeholders:

Include clinicians, practice managers, IT personnel, and patients in planning discussions.



Establish Collaborations:

Partner with NHS organizations, academic institutions, or Clinical Research Networks to support study design and implementation.

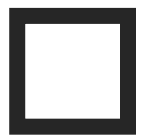


Patient and Public Involvement (PPI):

Involve patients and the public early to ensure the study addresses their needs and concerns.

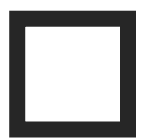


Step 4: Design the Pilot Study



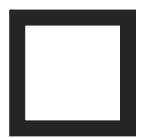
Define Objectives and Outcomes:

Set clear, measurable goals for what the pilot aims to achieve.



Develop Study Protocol:

Outline study design, participant criteria, data collection methods, and analysis plans.

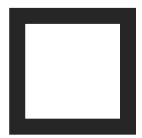


Set Success Criteria:

Determine what constitutes a successful pilot, including clinical outcomes, user satisfaction, and cost-effectiveness.

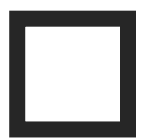


Step 5: Address Legal and Ethical Requirements



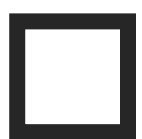
Ethical Approval:

Submit your study protocol to a Research Ethics Committee (REC) for review and approval. **(IF APPLICABLE)**



Informed Consent:

Develop comprehensive consent materials ensuring participants understand the study's purpose, procedures, risks, and benefits.



Data Protection Compliance:

Ensure adherence to the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018, including conducting a Data Protection Impact Assessment (DPIA).



Step 6: Secure Information Governance and Data Sharing Agreements



Data Security Measures:

Implement appropriate technical and organizational measures to safeguard personal data.



Data Sharing Agreements:

Establish formal agreements outlining data sharing terms between involved parties.

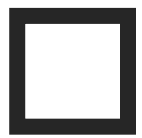


Complete the Data Security and Protection Toolkit (DSPT):

Demonstrate compliance with NHS data security standards.

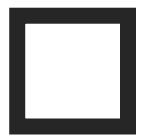


Step 7: Obtain Necessary Approvals and Support



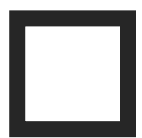
Health Research Authority Approval:

Obtain HRA approval for research involving NHS patients, staff, or data.



NHS Site Capacity and Capability Assessment:

Work with participating NHS sites to confirm they have the resources and infrastructure to support the study.



Engage with NIHR Clinical Research Network:

Seek support for study setup, recruitment, and delivery. **(If needed)**

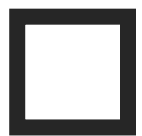


Step 8: Conduct the Pilot Study



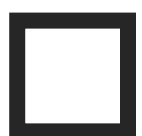
Training and Onboarding:

Provide comprehensive training to users of the HealthTech solution.



Implement the Technology:

Deploy the HealthTech solution in the selected primary care setting.



Monitor Progress:

Continuously monitor the study's progress, addressing any issues promptly.



Step 9: Evaluate Outcomes and Analyse Data



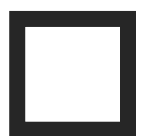
Data Analysis:

Analyse collected data to assess the HealthTech solution's effectiveness, safety, and user satisfaction.



Compare Against Success Criteria:

Determine whether the pilot met its predefined objectives.

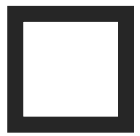


Gather Feedback:

Collect qualitative feedback from participants to inform future improvements.

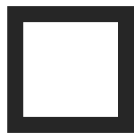


Step 10: Report Findings and Plan Next Steps



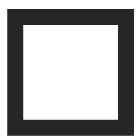
Disseminate Results:

Share findings with stakeholders, including NHS organizations, participants, and the wider healthcare community.



Decide on Scaling:

Based on pilot outcomes, determine whether to scale up, modify, or discontinue the HealthTech solution.



Plan for Wider Implementation:

If scaling, develop a comprehensive plan addressing resource needs, training, and ongoing evaluation