Ref: care.data/Programme Board Main Session/Paper 02
Title: care.data Project Initiation Document for Pathfinders
Author: Jill Sharples
Programme Board Sponsor: Eve Roodhouse, Programme Director
Purpose: The project initiation document (PID) is an extension and refinement of a number of documents prepared to shape the pathfinder stage of care.data. It brings together in one place information about scope, timelines, anticipated costs, risks and issues and the approach to evaluation and addresses key recommendations raised by the Major Projects Authority as part of the Project Validation Review carried out in April/May 2014.
Background: In February 2014, the decision was taken to delay the start of the extraction of primary care data from general practice following concerns raised by key stakeholders, in the media and across social media. Since then the programme has been listening to the views of patients, the public, GPs and stakeholders on how best to build trust and confidence in the programme. The first stage of this phased roll out will take the form of a discovery stage working with up to 250 pathfinder practices. This approach will allow NHS England (NHSE) and the Health and Social Care Information Centre (HSCIC) to work with a smaller number of GP practices to ensure that the programme understands what is required to support GP practices in meeting fair processing responsibilities, so that patients are aware of how their data will be used and the choices available to them. This is referred to as the pathfinder stage. The following papers have previously been presented to the board: • care data Planning Principles (23 September 2014) • care data Pathfinder Proposal (23 September 2014) • care data Pathfinder Success Criteria (23 September 2014) • care data Assurance Approval and Evaluation for Pathfinders (17 November 2014) The pathfinder documents have been extended and refined to form the project initiation document (PID)
Key Points: The project initiation document brings together in one place information about the scope, timelines, anticipated costs, risks and issues, approach to evaluation and success criteria for the pathfinder stage.
Desired outcome(s): For the programme board to approve this document at their meeting on 14 January 2015.
Circulation: Programme Board attendees only
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(P01306) Pathfinder Stage: Primary Care – HES Linkage

Project Initiation Document

Document Management

Revision History

Version	Date	Summary of Changes
0.1	01.12.14	Initial Draft
0.2	05.12.14	Revised draft following review of 0.1
0.3	09.12.14	Revised draft following review of 0.2
0.4	29.12.14	Update terminology from source documents and following review of 0.3
0.5	09.02.15	Update following changes suggested by Programme Board
1.0	16.03.15	Final Version

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
David Corbett	Programme Head - Data Delivery	02.12.14	0.1
Eva Simmonds	Business Case Programme Manager	02.12.14	0.1
David Corbett	Programme Head - Data Delivery	02.12.14	0.2
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Phil Bastable	Head of Marketing NHSE	31.12.14	0.3
David Corbett	Programme Head - Data Delivery	05.01.15	0.4
Donna Braisby	Programme Manager – PMO Controls	09.02.15	0.5

Approved by

This document must be approved by the following people:

Name	Signature	Title	Date	Version
Eve Roodhouse		Programme Director care.data		0.4
Tim Kelsey		SRO care.data programme		0.4
care.data programme board		care.data programme board		0.5
Tim Kelsey		SRO care.data programme		1.0

Glossary of Terms

Term / Abbreviation	What it stands for
ADASS	Association of Directors of Adult Social Services
BMA	British Medical Association
CCG	Clinical Commissioning Group
CQC	Care Quality Commission
DME	Data Management Environment
DoH	Department of Health
GPES	GP Extraction Service
HES	Hospital Episode Service
HSCIC	Health & Social Care Information Centre
IAG	Independent Advisory Group
IAO	Informatics Accountable Office
IG	Information Governance
IT	Information Technology
MHRA	Medicines and Healthcare products Regulatory Agency
MoU	Memorandum of Understanding
NHSE	NHS England
PHE	Public Health England
RCGP	Royal College of General Practitioners
NIB	National Information Board
SCIE	Social Care Institute for Excellence
SoS	Secretary of State
SRO	Senior Responsible Officer

Document Control:

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Contents

1 Purpose

The Project Initiation Document (PID) is an extension and refinement of a number of documents prepared to shape the pathfinder stage of care.data. It brings together in one place information about scope, timelines, anticipated costs, risks and issues and the approach to evaluation and addresses key recommendations raised by the Major Projects Authority as part of the Project Validation Review carried out in April/May 2014.

2 Project definition and scope

2.1 Background

Care.data is a programme of work which aims to increase the range and detail of information that is collected across all NHS funded services, then to securely connect that information together and make it available to those who plan NHS services, as well as to researchers, clinicians, medical charities and businesses that support the NHS to make services better. The first phase of this involves collecting and securely connecting information from GP practices to existing hospital information known as Hospital Episode Statistics (HES).

In February 2014 NHS England announced a six month extension to the proposed roll out of the care.data programme in order to raise awareness, listen and act on the views of patients, health professionals and key stakeholders, and to discuss both the benefits and risks involved.

This would enable time to be taken to raise awareness of the benefits of data sharing for purposes beyond direct care and the safeguards in place to secure patient data and to address the issue of ensuring the public are aware of their choices and are informed on how they can ‘opt out’.

During this “listening period” the care.data programme listened to, and worked with professionals and patients via a series of 150 listening events across the country. Views were sought from GPs, practice managers, councils, nurses, patient participation groups, local Healthwatch Groups, members of the public and other health professionals and campaign groups. The programme also established the care.data Advisory Group during this period.

The outcome of the engagement was a clear message that clarity was required about how personal information would be used, what information would be collected and how patients would be communicated to on their right to ‘opt out’. Additionally, it was clear that consideration should be given to the support required by GP practices to meet the fair processing requirements and successfully communicate these messages to support the introduction of care.data, and to implement care.data through a phased roll-out

The first stage of this phased roll out will take the form of a discovery stage working with up to 250 pathfinder practices. This approach will allow NHS England (NHSE) and the Health and Social Care Information Centre (HSCIC) to work with a smaller number of GP practices to ensure that the programme understands what is required to support GP practices in meeting fair processing responsibilities, so that patients are aware of how their data will be used and the choices available to them. This is referred to as the pathfinder stage.

The **‘pathfinder stage’** has been established as a project within the care.data programme, it will provide key information from which the programme team can learn from and assess the impact before progression into a “wider roll-out” and will adhere to the care.data planning principles in Appendix 1.

2.2 Commissioning organisation

The care.data programme is being commissioned by the National Information Board (NIB) on behalf of the entire health and social care system. The work of the NIB is overseen by the

Department of Health's Informatics Accountable Officer (IAO) through the National Information Director who chairs the Board.

The NIB defines and agrees the strategy, requirements and priorities for information technology across health and care. It makes sure that system leaders work together to deliver the framework for improving health and well-being through data and information technology. Its members include a wide range of bodies from health and care.

The NIB requested NHS England to act as lead commissioner on their behalf in relation to care.data, with accountability of Senior Responsible Owner (SRO). NHS England directed HSCIC to collect Primary Care data in December 2013[1] through powers provided by the Health and Social Care Act 2012.

2.3 Primary funding organisation

The primary funding organisation is NHS England. However, HSCIC is funding the work to enhance the existing Data Management Environment and to provide a Secure Data Facility for the pathfinder stage.

2.4 Scope

2.4.1 Objectives and deliverables

The objectives of the pathfinder stage were agreed as part of the pathfinder proposals document, which was developed with the care.data Advisory Group and approved by the Programme Board[2]. The specified objectives of the Pathfinder stage are to:

1. Test and refine resource packages so that GP practices understand how they can meet their fair processing requirements and have materials which support them in doing so. This will include materials which support GP practice staff in:
   a. understanding care.data e.g. the benefits/risks; the available choices for patients, what these choices mean; the difference between care.data and other data sharing etc.
   b. awareness raising e.g. materials within the practice; template text for websites/repeat prescriptions etc.
   c. administering the opt out process for example opt out forms
   d. responding to patients who have questions/concerns e.g. by providing or signposting patients to further information
   e. understanding how the extraction process works.
2. Assess existing national materials and identify changes that may need to be made to these e.g. existing FAQs, fair processing information materials that NHS England and HSCIC have available.
3. Test out and trial different approaches to communicating with patients and the public, including evaluation in terms of their costs and effectiveness. This will include materials which enable patients and the public to understand:
   a. how data will be used;
   b. their choices;
   c. objections and how they can opt out;
   d. what happens if they have already opted out; and,
   e. their rights to change their mind at any time.
4. Assess the impact on resources and services looking in particular at GP practices and Clinical Commissioning Groups while considering the effect on other parts of the overall service, this will specifically look at:

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[1] http://www.england.nhs.uk/wp-content/uploads/2013/09/item_5.pdf

[2] http://www.england.nhs.uk/wp-content/uploads/2014/10/caredata-pathfinder-proposal.pdf

   a. any additional burden on GPs and practice staff;
   b. any additional burden on Clinical Commissioning Groups;
   c. options as to how potential burden could be negated or eased e.g. through Local Enhanced Service contracts or Directed Enhanced Services; and,
   d. other factors such as through use of the data to reduce resource needs in other areas.
5. Provide and test enhanced guidance and resources specifically in relation to opt out processes.
6. Assess the level of patient awareness across a broad and diverse demographic group in discharging their rights and choices for data sharing.
7. Consider how local and regional structures/organisations can support awareness raising e.g. local Healthwatch/ Local Medical Committees (LMCs).
8. Explore how whole communities e.g. through Third Sector organisations such as charities and volunteer groups can be consulted and involved at the regional level to support awareness raising.
9. Establish if there are other potential routes to get information across to patients and the public.
10. Provide assurance of the technical aspects of the data extracts through the GP Extraction Service, demonstrating that the GP system suppliers have interpreted and implemented the extraction specification correctly.
11. Provide assurance regards process and controls in place to regulate and restrict the onward dissemination of the data that is extracted
12. Act as a key decision point to determine whether the care.data programme can proceed to the next stage in rollout to a wider selection of practices.
13. Identify how data collected from practices can be best utilised to feedback information and analysis that will support the pathfinder practices and CCGs, e.g. providing analysis such as comparator data and data quality analysis.
14. Explore with a limited number of research organisations using a secure data environment how the data may be used for research purposes and the potential for benefits to be realised (assuming General Practice Extraction Service Independent Advisory Group approval is given to enable access to data beyond commissioning.

2.4.2 Expected outcome and scale of business change

On the 6th October NHS England announced that GP-led clinical commissioning groups (CCGs) in four areas of the country would help develop the care.data programme as it moves into a ‘pathfinder stage’. These CCGs represent a maximum of 265 GP practices with a maximum population of 2 million patients. The programme took a targeted approach to the recruitment of CCG pathfinder areas. Each CCG voluntarily submitted detailed formal expressions of interests to the selection panel. The selection panel comprised of programme representatives, RCGP, BMA, Healthwatch England and NHS England's voluntary sector partners. The Programme Board endorsed the selection panel's decision and the Secretary of State cleared the proposals before the formal announcement of the CCGs. The participating CCGs are:

- Blackburn with Darwen
- Leeds North
- Leeds West
- Leeds South and East (Leeds forms a joint project across the 3 CCGs)
- Somerset
- West Hampshire

Communication Collateral

An initial set of draft core GP and patient-facing communication materials have been developed taking into account the combined feedback gleaned throughout the care.data ‘listening period’, such as from local and national events/meetings about the care.data programme and formal research (conducted by Ipsos MORI) with both members of the public and GPs/GP practice managers. The programme has now entered a period of co-production to further develop these materials with key stakeholders. The major stakeholders being the pathfinder CCGs themselves who have reviewed the draft materials and provided comments back to the programme team.

Reducing Burden

The pathfinder stage will be used to assess the burden on GPs and practices, including; the provision of information to patients on fair processing, the management of the opt out process and the management of the data extraction process. This will help to ensure resources and support are concentrated on getting it right with a defined population before a wider extraction of data is considered. CCG relationships with local Healthwatch, patient groups, local authorities and community organisations will be invaluable in engaging local stakeholders during the pathfinder work.

Information Safeguards

A further requirement emerging from the ‘listening period’ was to address concerns raised in relation to the protection of information. The rules around how data will be shared will be clearly stated before coded information is collected from pathfinder practices. During the pathfinder stage access to information collected will be restricted to a limited number of approved analysts (NHSE, HSCIC, PHE and CQC) in a new secure data facility to be established by the HSCIC.

HSCIC’s Senior Information Risk Owner has sanctioned the extension of existing services for the collection, processing and analysis of pathfinder data, hosted on HSCIC’s DME platform for a time limited period, and in response to the small scale of data collected during this stage.

Approval to commence fair processing and extraction of primary care data will be gained in two stages[3]:

1. Documentation and evidence which will be provided to gain the approval to commence the fair processing period and subsequently data extraction from pathfinders.
2. Evidence and evaluation which will be provided to measure success following the pathfinder stage in order to make a further decision to proceed beyond the pathfinder stage.

The extraction of data from pathfinder practices is subject to advice from Dame Fiona Caldicott, the National Data Guardian for health and care[4] and following the Secretary of State announcement that *“No data will be extracted from GP practice systems – including during the ‘pathfinder’ pilot stage of the programme – until sh*e (Dame Fiona) *has advised me that she is satisfied with the programme’s proposals and safeguards*[5]*”* and based on a decision to proceed being taken locally by Pathfinder areas and by the care.data Programme Board.

Any wider roll-out will be informed by a full evaluation of the outcomes of the pathfinder stage and will be scrutinised by the Independent Information Governance Oversight Panel (IIGOP).

2.4.3 Expected Outputs

The outputs from the Pathfinder stage are as follows:

1. An assessment of the level of awareness/understanding and attitudes of the professionals in GP practices, and the patient and public in the pathfinder areas;

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[3] Paper 05 care.data Assurance, Approval and Evaluation for Pathfinders 20141215

[4] https://www.gov.uk/government/news/national-data-guardian-appointed-to-safeguard-patients-healthcare-information

[5] https://www.gov.uk/government/speeches/innovation-and-efficiency?utm_source=twitter&utm_medium=social

    a. Ipsos MORI Insight
    b. regionally led research
    c. programme led research
2. A suite of communication materials and tools aimed at public (including hard to reach groups) and professionals;
    a. communication products, eg patient letters, leaflet & poster(s)
    b. a GP Tool kit
3. Fair processing HSCIC web pages for public viewing covering;
    a. how data will be extracted
    b. how it will be processed
    c. who will have access
4. An evaluation of the impact on wider data sharing of the opt out applying to all purposes beyond direct care.
5. Secure Data Facility;
    a. the use of a new facility within HSCIC for accessing pathfinder data
6. Pathfinder data extract linked to HES data;
    a. development of existing data extraction service
7. Data analysis to identify;
    a. early findings on the use of data,
    b. potential benefits
    c. limitations in the use of data
8. A review of technical capabilities giving consideration on;
    a. impact on current systems
    b. requirements to inform expansion to a national roll-out.
9. An Evaluation Summary Document

2.4.4 Exclusions from scope

The following are excluded from the scope of the Pathfinder stage.

1. Any activity beyond the pathfinder stage. Further rollout will be covered by a separate project initiation document and business case.
2. Costs and additional activity being carried out by NHS England or other NIB member organisations in support of care.data (e.g. analysis of data once available). It is expected that these organisations will provide separate justification for their activities via their own business planning cycles.
3. Extension of the existing HSCIC service to collect and process patient data. The HSCIC is supporting this Pathfinder activity by funding and providing this extension to meet the pathfinder requirement.
4. Other datasets that may be required as part of the care.data programme. It is expected that these dataset projects will be agreed through separate justifications for their activities within the care.data programme.
5. The GP Extraction Service (GPES) expansion of the GP dataset is out of scope; however, there are key dependencies on the GP Extraction Service in relation to the delivery of primary care data.

2.4.5 Project approach

The following sub-stages form the overall pathfinder stage;

1. Scoping and requirements gathering
2. Pathfinder recruitment and selection
3. Project mobilisation and planning
4. Co-production and practice recruitment
5. Print distribution and Education/Training of GP Practices
6. Fair Processing and Data Extraction
7. Processing of the data by HSCIC
8. Presentation of data in the secure data facility

9. Evaluation
10. Closure including lessons learned

2.4.6 Commercial considerations

Where suppliers are involved in the provision of the pathfinder activity (i.e. provision of communications materials and extraction of data) standard procurement practices will be used and any commercial considerations will be addressed in the subsequent business case for national roll out.

NHS England expenditure on research, communication materials and activity will be approved through their internal Efficiency Control Committee (ECC) and the Cabinet Office Efficiency Reform Group (ERG). These approvals are required prior to start of the procurement process.

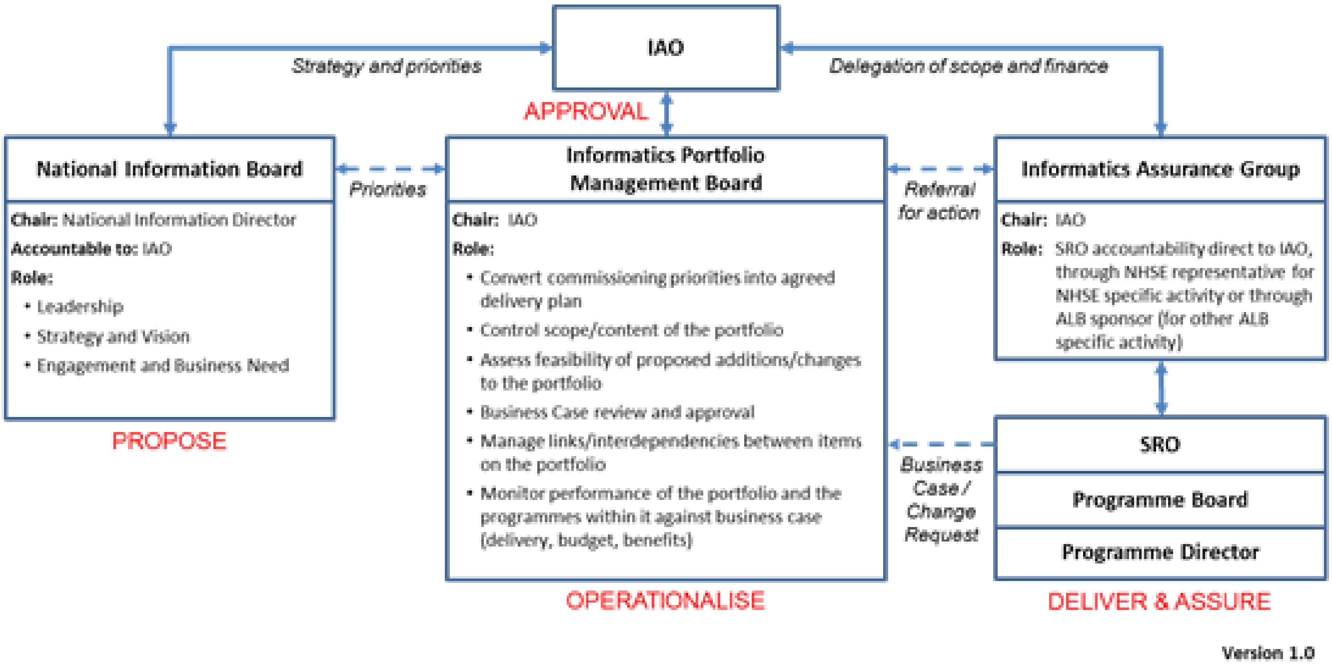
3 Project organisation

3.1 Senior Responsible Owner (SRO)

Tim Kelsey the National Director for Patients and Information, NHS England is the SRO for the Pathfinder stage.

3.2 Project governance

The care.data programme is governed in accordance with standard procedures and relates to the Informatics Accountable Officer as follows:



National Information Board
Chair: National Information Director
Accountable to: IAO
Role:
- Leadership
- Strategy and Vision
- Engagement and Business Need

Informatics Portfolio Management Board
Chair: IAO
Role:
- Convert commissioning priorities into agreed delivery plan
- Control scope/content of the portfolio
- Assess feasibility of proposed additions/changes to the portfolio
- Business Case review and approval
- Manage links/interdependencies between items on the portfolio
- Monitor performance of the portfolio and the programmes within it against business case (delivery, budget, benefits)

Informatics Assurance Group
Chair: IAO
Role: SRO accountability direct to IAO, through NHSE representative for NHSE specific activity or through ALB sponsor (for other ALB specific activity)

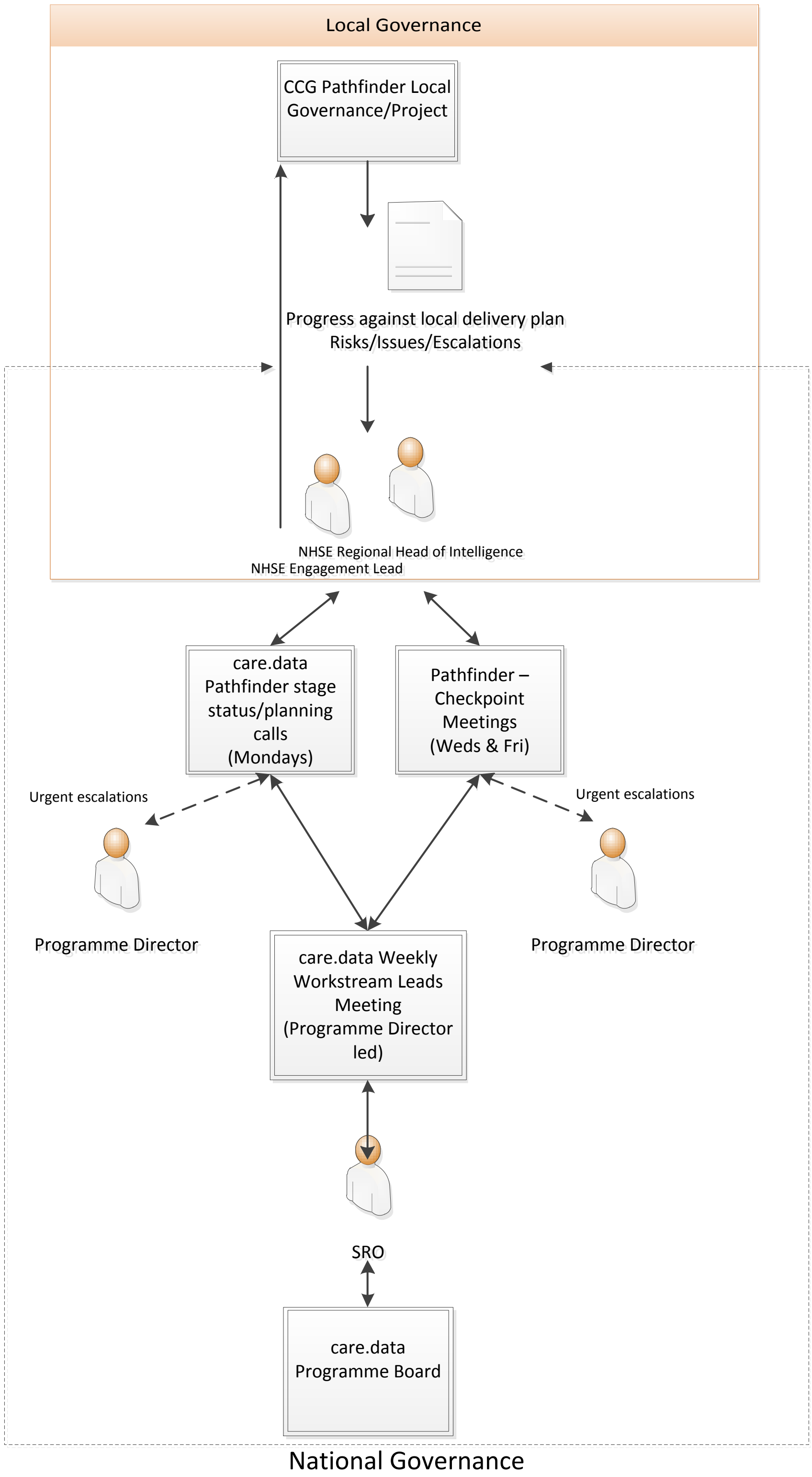
The pathfinder stage of the care.data programme is governed by the care.data Programme Board and Cabinet Office assurance is provided by the Major Project Authority. The care.data Advisory Group chaired by Ciaran Devane, CEO of the British Council, acts as a stakeholder engagement group and includes members from British Medical Association, Royal College of General Practitioners, HealthWatch and the Information Commissioners Office.

The purpose of the care.data Advisory group is to guide the development of the care.data programme and it is mandated to provide advice and recommendations to help ensure that benefits of the programme are understood and articulated, and that risks are equally understood, articulated, and have appropriate mitigation. The advisory group will make recommendations to the care.data programme board, which in turn reports to the IAO via the Informatics Assurance Group (Will Cavendish representing).

The Independent Information Governance Oversight Panel (IIGOP), chaired by Dame Fiona Caldicott, has agreed to advise the care.data Programme Board and Senior Responsible Owner on the first phase of the implementation of the programme in its role advising, challenging and reporting on the state of information governance across the health and care system in England. Dame Fiona Caldicott will advise the Secretary of State on proceeding with the Pathfinder extract in her role as the National Data Guardian for health and care.

The Pathfinder areas have local project teams of CCG and programme staff reporting to the local SRO (CCG Chair), with responsibilities laid out in a MoU with each CCG. Governance arrangements with CCGs for the pathfinder stage are as follows:

Communication/Escalation Process between Local and National governance



3.3 Project board

The project is governed through the Care.data Programme Board. The terms of reference of the care.data programme board are in Appendix 2.

The care.data programme board standard list of attendees and representing organisations is as follows:

Name	Organisation
Eve Roodhouse	HSCIC
Andy Williams	HSCIC
Tim Kelsey	NHS England
Dr Geraint Lewis	NHS England, Patients & Information
Prof John Newton	Public Health England
Simon Denegri	National Institute for Health Research
Peter Knight	Department of Health
Will Cavendish	Department of Health
David Knight	Department of Health
Tom Ward	Care Quality Commission
Dr Ian Hudson	MHRA
Neil Stutchbury	Monitor
Ciaran Devane (Observer)	British Council (previous Macmillan Cancer Support)
Bruce Keogh	NHS England
Sarah Schofield	West Hampshire CCG
Donna Braisby (secretariat)	HSCIC

4 Resource plan

Resource data has been extracted from current care.data financial forecasts[6] to identify resources with a substantive role in supporting the pathfinder stage. Additional resource from both HSCIC and NHSE support delivery of the pathfinder stage, but are not shown in the table below. A full breakdown can be viewed in the care.data financial forecast and tracker.

Pathfinder: Role title	2014:15 Full Time Equiv (FTE)	2015:16 Proposed Equiv (FTE)	Organisation
Regional Heads of Intelligence	2.4	2.4	NHSE
Regional Engagement Lead	5.0	12.0	NHSE
Communications	5.5	5.5	NHSE
Policy	3.0	2.0	NHSE
Data Delivery Programme Head	1.0	1.0	HSCIC
Data Delivery Programme Manager	1.4	2.4	HSCIC
Data Delivery Project Management	2.0	2.0	HSCIC
Senior Project Support	1.0	1.0	HSCIC

Note: Includes full list of resources deployed to the pathfinder stage as set out in the financial summary

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[6] Financial Summary Paper 20141224 and Care.data Summary 20141126.xls

5 Key stakeholders

Since the announcement of the ‘listening period’, in February 2014 over 150 engagement events and meetings have been held to better understand issues. The care.data team have engaged and consulted with key stakeholders to inform and develop plans and proposals for the pathfinder stage. A communication and engagement draft plan[7] sets out the approach with key stakeholders as follows:

Key players – work closely	**Active consultation**
- Health and Social Care Information Centre - Department of Health - Healthwatch England - British Medical Association - Royal College of GPs - Voluntary and Community Sector (VCS) - Information Commissioner’s Office - Media - GPs and GP practices - The Independent Information Governance Oversight Panel (IIGOP) - Dame Fiona Caldicott, National Data Guardian - Care.data Advisory group - Programme Board	- Public/Patients - NHS England staff (Particularly including Regional and area teams) - GPs and GP practices (all) - Ministers/MPs - Health Select Committee - Shadow Health Team - Health and Wellbeing Boards - Royal Colleges - Strategic partners and key stakeholders - Voluntary and Community Sector (VCS) - Medical Defence organisations - Civil Liberty Groups - Social care data groups (ADASS and SCIE)
Keep informed	**Monitor**
- Clinical Commissioning Groups - Clinical Support Units - Academic Health Science Networks - Shelford Group - NHS Clinical Commissioners - Provider Organisations - Think Tanks - Wider Clinical bodies - NHS Business Services Authority - Wider Civil liberty groups - Local Authorities	- Media - Social networks - Key opinion makers

Note: Draft format to be updated following FQ clusters and activities

The programme will continue to inform and involve these groups in reviewing and commentating on products and findings as the pathfinder stage progresses.

The care.data Programme is also working closely with the Information Commissioner’s Office (ICO) and will continue to involve and consult with the ICO as materials and products are developed through the pathfinder stage.

6 Initial business case

The pathfinder stage is fully funded by NHS England and the HSCIC. The pathfinder stage will inform the Primary Care-HES Outline Business Case. The following table sets out the estimated costs attributable to the pathfinder stage:

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[7] Pathfinder Comms and Stake Plan 281114.doc (Draft)

Care.data Programme Costs	2015/2016 £
NHS England costs to be covered by NHS England	1,690,582
HSCIC costs to be covered by NHS England	1,706,017
Total cost to be covered by NHS England	3,396,599
PoD Costs to be covered by HSCIC	715,000
Total Programme Costs	**4,111,599**

7 Benefits

The pathfinder stage supports the delivery of the overall care.data programme addressing concerns raised, working closely with a small number of GP practices to increase the chance of successful national roll out by:

- providing an evaluation of approach to the extraction of primary care data
- informing the achievability of the programme benefits.

The care.data programme benefits which the pathfinder stage forms part of will combine some of the coded information from patients' GP records with information held by NHS hospitals so that it can be used to:

- map diseases more quickly at a national level
- understand patients' journey through the health system
- see the outcomes of their treatments and address variations in care across the country
- improve the quality of care by monitoring adherence to national treatment guidelines
- plan where investment and changes are needed in NHS services.

The care.data programme will benefit the patient and public by:

- helping to ensure the highest standards of care and clinical safety are consistently met throughout the NHS and alert us to where standards drop, allowing us to take prompt action to improve patient safety
- ensuring the needs of patients, especially those with long term conditions, are met by helping us understand what happens to people cared for away from hospitals
- providing us with the vital information needed to assist and support research into new medicines, and the better treatment of disease

The care.data programme submitted an application to the GPES IAG in September 2014 to seek approval for the GP data extracted under care.data to be used for non-commissioning purposes. This application included a benefits plan containing case studies of real life benefits achieved through the use of patient data[8] , these benefits were discussed at the meeting on 11th September 2014 and published case studies providing examples of the benefits of how the data will be linked is as follows in Appendix 4:

8 Project controls

8.1 Reporting

Weekly Reporting

The CCGs report status and progress weekly via the Regional Heads of Intelligence /Engagement Leads who provide updates through to the Data Delivery workstream, a summary of which is included in the weekly and monthly highlight reports.

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[8] http://www.hscic.gov.uk/gpes/caredata

Workstream leads report progress to the care.data Programme on a weekly basis using the Weekly Workstream Report (WSR). The report is submitted to the care.data PMO and discussed at Programme Director level.

Monthly Reporting

Highlight reports are completed by each workstream lead and reported monthly to the care.data programme board. All reporting is managed and co-ordinated by the care.data PMO.

8.2 Tolerances

Tolerances for the pathfinder stage are in draft and have as yet to be confirmed but the following are recommended:

Tolerances category	Tolerance	Comments (where applicable)
Number of CCGs participating	A minimum of 2 CCGs Zero tolerance for 1 to 3. Item 4 is the "ideal" but has a tolerance in line with outcomes from Evaluation	In line with the CCG Selection Criteria to cover: 1. A mixture of practice size and support for care.data 2. Coverage of 3 out of 4 GP system suppliers 3. A mixture of population demographics 4. A mixture in maturity of data sharing systems

Note: 1. A minimum of 2 CCGs if they meet all selection criteria
Note 2. Milestone Tolerance has as yet to be agreed

The standard tolerance exception report available on the P3S Framework will be used to when it is forecast that a tolerance will be exceeded.

8.3 Delivery assurance

The Risk Potential Assessment (RPA) score for the care.data Programme is HIGH.

8.4 Risks and issues management

The pathfinder stage will manage risks and issues in accordance with the standard HSCIC polices:

1. HSCIC Risk and Issue Management Policy
2. HSCIC Risks and Issue Management Strategy and Framework
3. HSCIC Risks and Issue Management Process and KPI Guide

8.5 Business change strategy

The pathfinder stage will be used to inform the business change strategy and business case for a national roll-out of the primary care HES linked data.

8.6 Change Control

Change control will be managed in accordance with the HSCIC P3S Framework and with escalation to the care.data programme board and depending on value to the Corporate Assurance Panel (CAP)

If an increase in expenditure (beyond the budget that has been approved) is required for external suppliers for research or communications activity the increase in budget will need to be approved through NHS England's Efficiency Control Committee (ECC) and the Cabinet Office Efficiency Reform Group (ERG). These approvals will be required prior to start of any additional activity.

8.7 Quality management

Quality Management will be as outlined in the Planning Principles (see Annex 1), through engagement with stakeholders and the care.data Advisory Group. The pathfinder stage will be evaluated against agreed success criteria by the care.data Programme Board. The Programme Board will rely on the advice of the pathfinders themselves, the Advisory Group and the Independent Information Governance Oversight Panel (IIGOP) to assess success. There are no artificial deadlines for national roll-out, the programme will proceed only when the Programme Board is sure that the process is right.

8.8 Benefits management

The benefits will be managed as part of the overall care.data programme and as described in the care.data Programme Business Case.

8.9 Communication and stakeholder engagement

The pathfinder communications and engagement plan reflects the current position across national and regional activity encapsulating the overall pathfinder approach. A copy of the latest Communication and Stakeholder plan is available through the care.data programme office.

8.10 Initial project plan

The latest version of the Plan on a Page can be obtained from the care.data programme office.

9 Assumptions, dependencies and constraints

9.1.1 Planning Principles

Planning Principles are set out in the table below:

Ref	Description
1	The programme will take a phased approach to implementation and will work with between 100 and 500 GP practices (pathfinders) to test, evaluate and refine all aspects of the data extraction process ahead of any further (national) rollout. The objectives for and approach to the selection of the pathfinder practices, as well as the criteria to assess the success of the pathfinder stage, will be developed in partnership with key stakeholders, and signed off by the Programme Board.
2	Dame Fiona Caldicott and IIGOP will provide independent advice on the pathfinder stage to inform the development of the pathfinder stage and decisions about further rollout. Any advice will be shared with the Advisory Group and Programme Board.
3	The decision to proceed with fair processing and data extraction from the pathfinder practices will be taken by the Programme Board. This will be based on all the dependencies as described in the programme plan being met.
4	A package of communication materials and tools for the public, GPs and their staff will be co-produced with pathfinder practices and wider stakeholders. This will include straightforward descriptions and mechanisms for supporting the objections process for professionals and the public which must be agreed with the Secretary of State as previously requested by him. They will be properly evaluated and refined with the involvement of GPs, their practice staff and patients. This will not include a change to the clinical codes which have been used to capture objections in primary care to date to ensure that any objections recorded between autumn 2013 and the start of the pathfinder stage can be properly observed.
5	The rules around access to identifiable data or data which is potentially identifiable will be clearly articulated before data extraction from pathfinder practices commences and implemented before any data collected as part of the programme is made available to organisations outside of the HSCIC. This includes changes to primary legislation having received Royal Assent and associated Regulations having commenced before data is disseminated.
6	The HSCIC intends to deliver a secure data facility to support strengthened controls around data access. A roadmap for the development and delivery of such a service should be in place before data is extracted from pathfinder practices. Access to data collected from pathfinder practices will

Ref	Description
	only be available on HSCIC premises and only to analysts who will work within an early version of the secure data facility.
7	The Code of Practice for Confidentiality will be published by the HSCIC before data is extracted from pathfinder practices.
8	The HSCIC will deliver fair processing pages on their website for members of the public to support pathfinder practices, and therefore in advance of fair processing commencing. The fair processing pages will set out the data to be extracted, how it will be processed and who will have access to it. The fair processing pages will cover all data collected under the programme in the future.
9	The programme team will work to ensure that data to be extracted from pathfinder practices is available to analysts from research organisations, charities and others, in line with planning assumption (6) above. The constraints around access should be aligned to rules referred to in planning principle (5) rather than by organisation type.
10	The HSCIC and NHS England will put in place a formal agreement to set out respective roles as Joint Data Controllers for the data to be extracted. This will be in place in advance of data being extracted from pathfinder practices.
11	In order to ensure that the programme is on a firm foundation, the business case (Strategic Outline Case or equivalent agile methodology) for the overall programme should be developed and agreed (as a minimum) with the Programme Board before data is collected from pathfinder practices.
12	The pathfinder stage will be evaluated against agreed success criteria by the Programme Board. The Programme Board will rely on the advice of the pathfinders themselves, the Advisory Group and the Independent Information Governance Oversight Panel (IIGOP) (see principle (2) above) to assess success. There are no artificial deadlines for national rollout – the programme will proceed only when the Programme Board is sure that the process is right.

9.1.2 Assumptions

Key assumptions are as follows:

Ref	Description
1	Appropriate funding and resources will be allocated to prevent delays
2	Policy relating to the delivery of care.data and pathfinders remain in place for the duration of the pathfinder stage
3	Existing landing and staging environment meet the required business impact security levels.
4	There will be effective end-end technical approach available to account for project requirements.
5	The technical solution will support the Pathfinders programme scope and timescales.

9.1.3 Constraints

Key constraints are as follows:

Ref	Description
1	Time and availability of resources for implementation activities, there are limited staff resources across a range of internal and external organisations, which could impact timescales.
2	Time limited sanction to land and process data on existing ICT on an IL3 environment for 12 months
3	Key decision-makers may be difficult to contact to support the required multi-stakeholder approval process and/or when issues arise resulting in delays.
4	There will be effective end-end technical approach available to account for project requirements.
5	The technical solution will support the Pathfinders programme scope and timescales.
6	Political environment leading up to the election and impact of Purdah

9.1.4 Dependencies

Key Milestones and Dependencies[9] approved on 16th July 2014

Ref	Title	Description	Dependencies	Lead	Milestone Date
1	Strategic Capability Platform Phase 1 approved	Brief for phase 1 of Strategic Capability Platform (SCP) (infrastructure uplift in the HSCIC to enable appropriate data platform for care.data) approved by the SCP Project Board – to enable procurement, development and delivery to commence. This phase 1 development is via separate business justification. (This is now approved by SCP Project Board and by HSCIC Portfolio Board).	SCP Project Board and HSCIC Portfolio Board approval (HSCIC governance).	Care.data Programme Team	Completed (Approved May 2014) (Note SRO confirmed in August 14 superseded by Pathfinders on DME)
2	Marketing and research funding approved	Department of Health and Cabinet Office approval for the marketing spend	Cabinet Office approvals body (ERG).	Care.data Programme Team	Completed (Approved early June 2014) Mail out spend approved by Cabinet Office Dec 2014
3	Commencement Order of CAG Elements of Care Bill	Commencement of Order of Confidentiality Advisory Group (CAG) elements of Care Bill & associated elements (i.e. receives Royal Assent).	Department of Health (outside of care.data).	Department of Health	Completed (Received Royal Assent late May 2014)
4	Marketing, research and stakeholder events launched	Funded marketing supported by regional stakeholder events. Research activity commenced to support engagement campaign.	Approval of funding (dependency on milestone 2 above).	Care.data Programme Team (Phased Extension workstream)	Completed
5	Pathfinder objectives and selection approach agreed	Objectives, the approach to GP pathfinder practice selection (including the criteria) to be agreed and approved by Programme Board with a clear plan of delivery (selection).	Approval by Programme Board. Advisory Group consultation (anticipated sub-group in June). IIGOP consultation. GP consultation.	Care.data Programme Team	Completed (Board approval secured 25 June)
6	Pathfinder practices selected	GP practices selected and fully engaged with appropriate communication and delivery plans available.	*(dependency on milestone 5 (approach) above)*	Care.data Programme Team	September 2014
7	Pathfinder stage success criteria agreed	Agreement and documentation of the success criteria to be met (baselined for measure where appropriate) to enable the success of the forthcoming pathfinder stage	Pathfinder stage success criteria approved Programme Board. IIGOP consultation and agreement.	Care.data Programme Team	September 2014

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[9] http://www.england.nhs.uk/wp-content/uploads/2014/10/caredata-planning-principles.pdf

Ref	Title	Description	Dependencies	Lead	Milestone Date
		to be evaluated.	Advisory Group consultation. Will be informed by research work (for engagement effectiveness elements of evaluation).		
8	Decision made to proceed to fair processing and data extraction	The decision to proceed with fair processing and data extraction from the pathfinder practices will be made by the Programme Board and will be based upon a number of dependencies being met.	Programme Board decision on go-ahead and communicated with plan to implementation.	Care.data Programme Team	Date tbc (when Board deems dependencies are met)
9	Primary Care pathfinder data extract launch	Data extract commenced for pathfinder GP practices with linkage to HES.	As per date confirmed following Board decision (see milestone 8 above). Data Guardian Advice to SoS to proceed		Date tbc
10	Assurance of pathfinder stage complete	IIGOP assurance complete and recommendations made to Programme Board.	(Dependency on milestone 7 above).	tbc (Programme Director currently owns)	Date tbc
11	Decision and definition in relation to future implementation stages	Following the pathfinder stage, decisions and further definition will follow regarding next steps and future stages (including potentially to national rollout, if deemed successful)	Recommendations as made to the programme Board to enable them to make informed decisions re future Data Guardian Advice to SoS to proceed (dependency on milestone 10 above).	tbc (Programme Director currently owns)	Date tbc

Documentation and evidence to assist decision for approval to commence Fair Processing and Data Extraction[10] (draft awaiting final Board approval)

Ref	Outcome	Description	Deliverable	Owner	Approver	Date of Approval
1	Achievement of Planning Principles	Evidence for board to consider achievement of the planning principles including: • HSCIC Code of Practice published • HSCIC fair processing pages live on the website • Joint data controller agreement in place • Business case endorsed by the programme board to enter HSCIC/NHS England/Government Department assurance and approvals • Position statement regarding care bill secondary legislation	An evidence based board paper from the programme confirming that the other dependencies as listed in the Planning Principles document have been achieved and adhered to	Eve Roodhouse	Programme Board	13/05/2015

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[10] Paper 04 care.data Assurance Approval and Evaluation for Pathfinders

Ref	Outcome	Description	Deliverable	Owner	Approver	Date of Approval
		• Revised Privacy Impact Assessment for NHSE				
2	CCG View	Each pathfinder CCG to provide a summary statement which are expected to include: • GPs are content with the communication activities/materials that are to be delivered, and with the approach that is to be followed • The CCGs and practices understand the process for data extraction. • A statement from the local Healthwatch group(s)	CCG View Board Paper	David Corbett	Programme Board	13/05/2015
3	Independent Assurance	Summary report produced by National Data Guardian and IIGOP and presented to care.data programme board covering: • Introduction • Role of National Data Guardian and IIGOP (including development of the proposals for the pathfinder stage, the role leading up-to testing of communications, and planned role through to the end of the pathfinder stage, and evidence considered in informing the report and its conclusions, signed off by National Data Guardian and IIGOP). • Summary of the planned process followed for the pathfinder stage including assurances National Data Guardian and IIGOP are content with the communication materials that are prepared and planned approach.	IIGOP Report	Alan Hassey	IIGOP (Alan Hassey in attendance at the Programme Board)	22/12/2014
4	Programme Team Assurance	Programme team assessment of the position against the questions and conditions set out in the IIGOP report published on 18 December 2014.	Response to IIGOP report	Eve Roodhouse	Programme Board	13/05/2015
5	Communication Materials	Programme Board to review and approve the communication materials to be used by pathfinders.	Approval of communication materials	Phil Bastable	Programme Board	31/03/2015

10 Risk and issue log

Key top 10 risks recorded on the tracking database for the pathfinder stage are as follows[11]:

Ref	Risk/Issue Title	Risk/Issue Description	Mitigation
R15482	Overstretched Resources	Resources are becoming overstretched as there is an increasing amount of work to support the additional demands of the pathfinder stage and patient objections implementation. Which may lead to activities not being delivered in a timely manner	Recruit additional resources for Patient Objections
R15884	Negative Media Portrayal;	There is a risk that negative media coverage could arise during the pathfinder stage which has the potential to lead to significant delays in the programme, costs could rise and damage to the reputation of the HSCIC and NHS England.	1. Publish relevant documents in a timely manner 2. Suitable, easy to access, website for informing the public to be set up 3. Publication of the Engagement Summary (formerly known as "You said, We did") 4. Regular updates to the Health Select Committee and Secretary of State 5. Engagement with advisory group, stakeholders and media plan monitoring
R15890	Low levels of GP uptake with Pathfinder stage	Despite a large amount of engagement work taking place (with pathfinder CCGs and regional heads of intelligence) to ensure GP engagement in the pathfinders, there is a risk that GPs may disengage from the pathfinder process. Leading to a delay in the pathfinder stage or result in objectives not being met.	1. Engagement, tracking and follow-up with CCGs / local areas through Pathfinder stage. 2. Obtain legal advice regarding legality of GPs opting out their entire practice. 3. Identify clinical advocates/champions at a national and local level. 4. Engage with Colleges and professional associations to ensure that their input shapers development of the pathfinder stage.
R15949	No approved business case for the Programme	There is a risk that the Business Case will not be endorsed in time for the Pathfinder stage and approved before the General Election (purdah). Leading to a delay in the pathfinder extraction	1. Recruit resource to support development of Business Case and benefits lead. 2. Resolve issues regarding the positioning of the care.data programme and the HSCIC response to that programme and other initiatives. 3. Work with DH and other stakeholders to develop an IAAP that supports approval ahead of purdah. 4. Engage early with stakeholders to gain input and buy in to the Business Case content.
R15978	Primary test data not available	There is a risk that primary care test data may not be developed/made available in time to support the testing of the platform.	Determine how suitable test data could be established to support the testing of this solution.

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[11] HSCIC Tracking Database, risks impact level High/Very High and Likelihood Possible/Likely

Ref	Risk/Issue Title	Risk/Issue Description	Mitigation
R15996	Complex Approval Process	There is a risk that delays could occur in the proposed plans for pathfinder extraction if the complex approval process is not managed effectively.	1. Complete an IAAP to map and monitor the approvals process for the business case 2. Ensure key stakeholders are involved throughout the processes (where approvals are required) to prevent delay 3. Escalate any unnecessary approvals process through the Programme Director 4. Assurance, Approvals & Evaluation document to be presented to Programme Board to outline the complexity of the approvals process. (Jan 2015)
R16039	Cost Implications: Pathfinder Letters	The cost of sending a letter to each patient in the remaining CCGs post pathfinders is significant and could set a precedent for the requirement to send a letter in subsequent datasets. This may lead to programme objectives not being met	1. Provide costing based on assumptions to the programme team 2. Add costs into the financial business planning between HSCIC & NHS England 3. Raise with the Programme Board during the evaluation and consideration to proceed stage
R16061	IIGOP Report Recommendations	There is a risk that pathfinders may not be able to meet the criteria required by the IIGOP report leading to a delay in processing and subsequent data extraction.	1. Internal review of the criteria /requirements arising out of the report and a plan to respond, take action. 2. Review report with CCGs to gain their view on how best to respond to the report.
R16099	Fair Processing – Approval to Proceed	There is a risk that the programme will be unable to secure local approvals to move into fair processing in timeframe (including to secure agreement on materials) leading to a delay in the pathfinder stage	1. Work with pathfinders to agree timeframe and plan to obtain local approvals.
R16132	Purdah / Election	Due to the critical timing of the pathfinder stage there is a risk that the election 'purdah' will effect essential decisions for the programme to progress	1. Ensure that fair processing and public polling for the pathfinder stage are concluded before purdah commences 2. Monitor progress of the pathfinder stage using critical path / milestones

11 Evaluation and Lessons learned

11.1.1 Evaluation

An evaluation report will be authored by the care.data programme but will be developed with input from stakeholders in pathfinder areas, along with national stakeholders. The report will use evidence captured through the pathfinder stage including information provided into the programme board from IIGOP, and research and insight conducted by Ipsos MORI the participating CCGs and the programme.

The evaluation and report will assess whether the objectives of the pathfinder stage were delivered and whether the success criteria were met. The report will also include conclusions and recommendations for future stages of the care.data programme.

An outline structure and timetable for the report will be agreed by the programme board in January 2015, and authors for each section of the report will be agreed. The report will be submitted to the care.data programme board, and will help to inform the board's decision for moving out of the pathfinder stage

11.1.2 Lessons learned

Lessons learned will form part of the Evaluation Report in addition to the use of standard P3S Framework templates.

12 Acceptance criteria

The pathfinder stage success criteria to support the decision to progress to roll-out are in development and for agreement[12]:

Ref	Outcome	Description/Evidence
1	There is a package of communications materials and tools which is endorsed by GPs and practice managers for the next stage(s) of roll out (with an acceptable level of improvements which may be identified).	GPs and practice managers feel that they were supported in delivering their fair processing responsibilities with high quality communication materials for their patients and for them. For example: a. They knew what support was available to them and were able to access communications materials as required. b. They could confidently answer questions raised by patients. c. They understood how the extraction process would work.
2	There is a package of communications materials and tools which reaches all citizens and provides adequate information about the proposed data sharing. Further this package is endorsed by practice participation groups for use the next stage(s) of roll out (with an acceptable level of improvements which may be identified).	a. All patients registered at a pathfinder practice received a personalised communication e.g. letter/text/email. b. Materials are accessible e.g. available in easy read and braille and supported by local and national voluntary groups. c. Detailed information is available to those who want to access it, i.e. the exact details of what will be extracted, how data will be stored etc. d. Local communities and stakeholders feel the communications were effective
3	The technical solution has worked as planned with no issues requiring resolution before the next stage(s) of roll out.	The GPES extraction process and the subsequent landing, linking and presentation of data in the Secure Data Facility work to specification.
4	There is a good understanding of the effort required by CCGs, GPs and Practice Manager to support data sharing for care.data	The effort required in terms of: burden on GPs and practice managers; cost of producing communications materials and tools; and, local engagement, is understood to ensure that an informed decision as to the next stage(s) of roll out can be made.
5	There is some initial analysis of the linked dataset including an indication of the quality of the data.	Early view of the potential benefits of the dataset as well as any limitations to inform next stage(s) of roll out.
6	The Independent Information Governance Oversight Panel (IIGOP) and Dame Fiona Caldicott are content that the processes followed have been sound and that the programme should proceed to the next stage(s)	NB: Exact description to be discussed and agreed with IIGOP and Dame Fiona Caldicott.

The adherence to planning principles and achievement of success criteria will be assessed as part of the Evaluation of the pathfinder stage.

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[12] Paper 11 care.data pathfinder Success Criteria DRAFT 20140923.pdf

13 Appendix 1: Planning Principles

20140826 care data
Planning Principles.pd

14 Appendix 2: Programme Board TOR

The latest version of the Programme Board Terms of Reference can be found here: http://www.england.nhs.uk/wp-content/uploads/2015/02/cd-prog-brd-tor.pdf

Paper 03 Programme
Board ToR v1.2 2015

15 Appendix 3: Benefits Plan

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.data_addendum_v2.