

SUMMARY REPORT

MedTech for One Healthy Baby

Workshop – 18 September 2018

1. Background	2
2. Process	2
Stakeholder Mapping	2
Strategic Roadmapping	2
Ecosystem Modelling	2
3. Outcomes	3
Exploration 1: Data linkage from conception to delivery: risk assessment & data integration	3
Proposal	3
Why we want to do this	3
Where we are now	3
Where we want to be	3
How we will get there and barriers to implementation	3
Exploration 2: Smart fetal assessment	3
Proposal	3
Why we want to do this	3
Where we are now	3
Where we want to be	3
How we will get there and barriers to implementation	4
Exploration 3: Service Delivery	4
Proposal	4
Why we want to do this	4
Where we are now	4
Where we want to be	4
How we will get there and barriers to implementation:	4
4. Next Steps	4
5. References: weblinks	5
6. Appendices	6
Appendix 1: Attendance List	6
Appendix 2: FINDINGS Ecosystem Modelling Workshop (08.08.18)	6
Appendix 3: POPULATED LANDSCAPE Strategic Roadmapping Workshop (18.09.18)	6
Appendix 4: CHART Proposal	6

1. Background

In 2015 there were 3,147 stillbirths and 2,052 neonatal deaths (babies who died <28 days) in England and Wales; 1000 infants died unexpectedly or were left with serious brain injury¹. Although there has never been a safer time to have a baby, the UK has one of the highest stillbirth rates amongst high-income countries. In 2015 the Secretary of State announced a national ambition to half stillbirths and neonatal brain injury by 2030²; in 2017, he announced that this ambition would be brought forward to 2025. The MBRRACE-UK Perinatal Mortality Surveillance Enquiry, published in 2017 highlighted that 1 in 20 stillbirths and neonatal deaths is labour-related and that in 80% of cases different care might have prevented the baby's death³. Of the problems highlighted, recognising when a woman moved from early to established labour and issues regarding fetal heart monitoring during labour were identified as causing delays in the prompt delivery of the baby.

The NIHR Brain Injury MedTech Co-operative Perinatal and Paediatric theme lead Professor Topun Austin, in collaboration with Ms Michele Upton (NHS Improvement, Clinical Lead for Maternity); agreed to support NHS England National Clinical Director for Women's and Maternity (Dr Matthew Jolly) by bringing together key stakeholders in perinatal care and biomedical engineering. The purpose of this workshop was to look at some of the real-world challenges around antenatal and perinatal care and identify where technology could be developed and utilised to improve the care of mothers and their babies.

The NHS Long Term Plan, published 7 January 2019, has further committed to the national ambition: "Through the Long Term Plan, the NHS will accelerate action to achieve 50% reductions in stillbirth, maternal mortality, neonatal mortality and serious brain injury by 2025." (p47).

2. Process

Stakeholder Mapping

To ensure appropriate representation from disciplines and sectors, the identification of the attendees list was iteratively developed in conjunction with the three leads (as above). Please see appendix 1 (attendance list).

Strategic Roadmapping

This process is used to advance strategic objectives, by addressing three fundamental questions⁴:

1. Where do we want to go?
2. Where are we now?
3. How do we get there?

The workshop, held on 18 September 2018, facilitated three structured outputs, in order to identify and prioritise areas of unmet need that are to amenable technology-based solutions and outline project proposals:

1. **Landscape Development:** Split by time periods, the group were asked to populate the following fields in pairs, using post-it notes (see appendix 1):
 - Why: Trends and Drivers
 - What: Patient Pathway Outcomes
 - How: Research Themes and enabling Projects
2. **Topic Selection:** The landscape outcomes were then grouped in to themes.
3. **Topic Development:** Through use of the Topic Exploration templates, 4 groups developed high level project proposals (see below), 2 of which have been combined for simplicity.

Ecosystem Modelling

The Ecosystem mapping approach has emerged from the Institute for Manufacturing (IfM, Dept of Engineering, University of Cambridge) Cambridge Service Alliance - a partnership which since 2010 has involved for example BAE Systems, Caterpillar, GEA, IBM, Pearson, Zoetis and CEMEX.

Ecosystem mapping facilitates the examination of complex networks of organisations, the value each member creates and risks taken on as a means of identifying potentially valuable players and new relationships, together

with potential new value propositions and solutions which may be available from alliances and partnerships. The workshop based and highly participative approach was applied to in the preparation for the One Healthy Baby workshop on 8 August 2018, in Cambridge. Please see appendix 2.

3. Outcomes

Exploration 1: Data linkage from conception to delivery: risk assessment & data integration

Proposal: to produce a seamless data linkage pipeline from conception to delivery for all pregnant women in the UK; this will enable us to a) *identify high risk pregnancies at an early stage* and then b) *provide the capacity to develop artificial intelligence (AI) algorithms* to be used at a population level to enable accurate risk assessment and potentially timely interventions.

Why we want to do this: as part of the national ambition to reduce stillbirths and perinatal brain injury, the ability to identify and monitor the high-risk pregnancy is vital. Using data to develop a personalised medicine approach to pregnancy is a key component of this.

Where we are now: currently data exists in both analogue and digital forms with poor linkage between different aspects of the care pathway (e.g. community midwife records, hospital records, imaging etc). This poses challenges for healthcare professionals to track the whole journey through pregnancy. A lack of data linkage across the population of patients prevents the development of smart algorithms to assess risk and predict complications.

Where we want to be: to have a seamless electronic healthcare data infrastructure from conception to delivery for all pregnant women and for that data to be aggregated into large data repositories to enable AI algorithms to be developed.

How we will get there and barriers to implementation: there are two key stages in developing this strategy. Firstly, a seamless integrated data pipeline needs to be developed following the patient journey through pregnancy. This will involve mapping existing data repositories, in line with associated guidelines and processes, and their compatibility with data aggregation. Any potential gaps identified in data collection will also be addressed. Once this pipeline has been established then the second stage will be to develop a central data repository into which data is aggregated and from which the data can be accessed.

The approach be piloted on a small scale and then opened up to developers and industrial partners to help develop an integrated data landscape. This fits in with the NHS Digital Data to Drive Improvement. We will need to ensure transparency and strong data governance and ensure compatibility with electronic records across the NHS; this will require significant infrastructure development costs.

Exploration 2: Smart fetal assessment

Proposal: to develop the 'virtual' midwife who has access to all relevant data (see proposal 1) and develop new 'intelligent' image reconstruction algorithms which improve prediction of risk and improve intrapartum monitoring to assess fetal compromise during labour.

Why we want to do this: continuity of care has been shown to be beneficial to mothers; while face-face visits by a single mother is prohibitively expensive, a 'virtual' midwife with access to all relevant data will be able to communicate remotely with a larger number of women. Improving the technology to assess fetal growth and intrapartum health will enable more accurate stratification of high-risk mothers.

Where we are now: current challenges are that multiple midwives will see a mother during pregnancy which limits continuity of care; current imaging does not predict future growth and hence risk; current intrapartum monitoring is not particularly predictive.

Where we want to be: to develop a system which provides the continuity of care and improves prediction during the pregnancy and during labour and delivery. This approach can be viewed as 'zooming' into the high-risk pregnancy and delivery from the overview of the 'virtual midwife' through to specific biomarkers during high-risk labour.

How we will get there and barriers to implementation: the workstream in developing the virtual midwife represents the healthcare professional view of the data linkage theme above. The ability to integrate data and develop AI approaches to risk stratification will need to be translated into a user-friendly interface to be used by midwives. Technological innovation in imaging science is required to develop 'intelligent' imaging systems which can predict future trajectories, by inputting demographic, biophysical and other relevant information into image reconstruction algorithms.

New intrapartum monitoring systems need to be designed and developed and need to gain acceptability and validity for use in labour.

Exploration 3: Service Delivery

Proposal: To develop an integrated record and process management system that ensures healthcare records during maternity are integrated and that resources are available at all stages of the maternity pathway

Why we want to do this: The integration and oversight of processes and specialities in the maternity pathway is poor. When pregnancies become high risk or there are issues arising at delivery there has often been no planning of the availability of resources in NICU or other support services. The process of handovers is poorly defined with no clear understanding of good system models and design. We want to ensure that poor outcomes are not associated with the lack of specialist resources at any point in the pathway. We want to deliver the right care at the right time.

Where we are now: There is no single point of contact or oversight in the maternity pathway. There are no processes which identify available resources linked to identified and unidentified risks throughout the pregnancy but especially at delivery. There is currently no joined up delivery of services in the maternity pathway.

Where we want to be: We want to develop a system that brings together all healthcare records and interventions throughout the maternity pathway. A system which estimates risks to the mother and baby during the pathway and especially at delivery and uses predictive algorithms to optimize resources to ensure the right specialist staff are available at the required time to deliver a healthy baby.

How we will get there and barriers to implementation:

There are a number of key steps to deliver this objective:

1. Model existing maternity services and infrastructure to understand the personnel and processes currently used especially linked to current services linked to good and less good outcomes.
2. To investigate actions required to bring maternity healthcare records into a single accessible platform.
3. To improve the risk assessment for the mother and baby during pregnancy, including inputs from the mother through a mobile application.
4. Develop an AI type tool to ensure that medical interventions are available and accessible linked to known risk assessments.
5. Deliver a dashboard type device to inform maternity services of potential unmet needs in service delivery and provide the data to correctly configure services dynamically.

4. Next Steps

Having developed 3 exploratory pathways we now wish to optimise these outputs to develop a final workstream that could potentially attract funding to assist the national ambition to reduce stillbirths and neonatal brain injury.

We have previously collaborated with Professor John Clarkson and Dr Ian Hosking at the Engineering Design Centre at the University of Cambridge, who specialise in systems engineering approaches to healthcare design.

The team have developed CHART (Cambridge Healthcare Advanced Risk Tool) (appendix 4). This tool produces a computational model of a clinical system that helps identify, quantify and prioritise risk. We therefore propose

to set up a workshop with key stakeholders to discuss the application of CHART to the pathways developed on 18th September.

5. References: weblinks

1. <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/bulletins/birthsummarytablesenglandandwales/2015>
 2. <https://www.gov.uk/government/news/new-ambition-to-halve-rate-of-stillbirths-and-infant-deaths>
 3. <https://www.npeu.ox.ac.uk/downloads/files/mbrace-uk/reports/MBRRACE-UK%20Intrapartum%20Confidential%20Enquiry%20Report%202017%20-%20final%20version.pdf>
 4. Hamilton C, Maw A, Gill A, *et al*. Paediatric neurorehabilitation: finding and filling the gaps through the use of the Institute for Manufacturing strategic roadmapping method. *BMJ Innov*. doi:10.1136/bmjinnov-2017-000202
- Each Baby Counts 2015 – full report: <https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/each-baby-counts-2015-full-report.pdf>
 - Each Baby Counts Anaesthetic report (June 2018): <https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/each-baby-counts/ebc-anaesthetic-report.pdf>
 - MBRRACE-UK website: <https://www.npeu.ox.ac.uk/mbrace-uk/reports> (they publish 3 sets of reports – maternity, perinatal morbidity and perinatal mortality – these latter two are more appropriate for our work)
 - Perinatal Mortality 2013 - 2016 - <https://www.npeu.ox.ac.uk/mbrace-uk/reports/perinatal-mortality-surveillance>
 - Perinatal morbidity 2013 - 2016: <https://www.npeu.ox.ac.uk/mbrace-uk/reports/perinatal-mortality-and-morbidity-confidential-enquiries>
 - maternal mortality – 2014 -2016 - <https://www.npeu.ox.ac.uk/mbrace-uk/reports/confidential-enquiry-into-maternal-deaths>
 - NHS Resolution: Five Years of Cerebral Palsy Claims: [file:///C:/Users/Michele.upton/Downloads/Five-years-of-cerebral-palsy-claims_A-thematic-review-of-NHS-Resolution-data%20\(2\).pdf](file:///C:/Users/Michele.upton/Downloads/Five-years-of-cerebral-palsy-claims_A-thematic-review-of-NHS-Resolution-data%20(2).pdf)
 - Saving Babies Lives care bundle evaluation: <file:///C:/Users/Michele.upton/Downloads/evaluationoftheimplementationofthesavingbabieslivescarebundleinearlyadopterhstsinenglandjuly2018-2.pdf>

6. Appendices

Appendix 1: Attendance List

NAME	ROLE	ORGANISATION
Dr Catherine Swann (PM Only)	Deputy director – maternity and community	Public Health England
Dr Gopi Menon	Consultant Neonatologist	NHS Lothian
Dr Matthew Jolly	National Clinical Director for the Maternity Review and Women's Health, NHS England	NHS England
Dr Peter Jarritt	Deputy Director – MedTech Evaluation	NIHR Brain Injury MedTech Co-operative
Mr Ben Austin		Parent representative
Mr Edward Morris	Vice President	Royal College of Obstetricians & Gynaecologists
Mr Nathaniel Mills	NHS Innovation Manager	NIHR Childrens & Young People
Mr Ravi Chana	MedTech Lead: National and International	NIHR Office for Clinical Research Infrastructure / Department of International Trade
Mr Tony Kelly	Consultant Obstetrician	Brighton & Sussex University Hospitals NHS Foundation
Ms Carolyn Young	Specialised Commissioner - Trauma Care	NHS England
Ms Karen Todd	Senior Maternity Safety Policy Advisor	Department of Health & Social Care
Ms Mandy Forrester	Head of Quality Standards	Royal College of Midwives
Ms Mehali Patel	Senior Research Officer	Sands: Stillbirth and Neonatal Death Charity
Ms Michele Upton	Head of Maternity and Neonatal Transformation programmes	NHS Improvement
Ms Rachel Scanlan	Standards Advisor	Royal College of Midwives
Prof Topun Austin	Consultant Neonatologist	Cambridge University Hospitals NHS Foundation Trust
Professor Flora Wong	Consultant neonatologist, Monash Newborn Associate Professor, NHMRC/CP Alliance Career Development Fellow	Hudson Institute of Medical Research/Monash University, Australia
Professor Florian Urmetzer	Dept of Engineering	University of Cambridge
Professor James Walker	National Professional Advisor (Maternity)	Care Quality Commission (CQC)
Professor Jenny Kurinczuk	Professor of Perinatal Epidemiology	University of Oxford
Professor Marian Knight	NIHR Professor of Maternal and Child Population Health	University of Oxford
Apologies:		
Dr Alexis Joannides	Deputy Director - Clinical Informatics and Registries	NIHR Brain Injury MedTech Co-operative
Dr Dominik Moeslein	Dept of Engineering - Institute for Manufacturing	University of Cambridge
Dr Samantha Steele	National Obstetric Clinical Fellow - Early Notification Team	NHS Resolution
Dr Sue Broster	Lead Specialist Consultant: Acute Neonatal Transfer Service (ANTS), Deputy Medical Director	Cambridge University Hospitals NHS Foundation Trust
Mr Roger Carter	Programme Manager - Developing Digital Maturity	NHS Digital
Ms Julia Gudgeon	Clinical Advisor (Midwife) - Digital Maternity Programme	NHS Digital
Professor Derek Tuffnell	Consultant-Obstetrics & Gynaecology	Bradford Teaching Hospitals NHS Foundation Trust

See Separate Attachments

Appendix 2: FINDINGS Ecosystem Modelling Workshop (08.08.18)

Appendix 3: POPULATED LANDSCAPE Strategic Roadmapping Workshop (18.09.18)

Appendix 4: CHART Proposal

ECOSYSTEM MAPPING & CAPABILITIES

08 August 2018
Cambridge



WORKSHOP RESULTS



National Institute for
Health Research

RECAP OF THE WORKSHOP ON AUGUST 8



Objective



Use ecosystem mapping methodology to discuss the following question:

How can technology support the Halve It campaign to reduce stillbirths and neonatal brain injury?



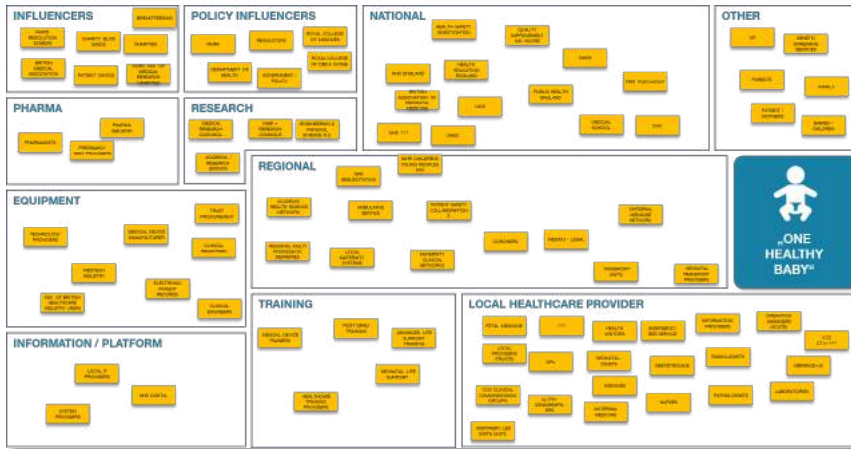
Participants



- **Professor Topun Austin**, Head of Evelyn Perinatal Imaging Centre, Rosie Hospital, Cambridge
- **Michele Upton**, Head of Maternity and Neonatal Transformation Programmes, NHS Improvement
- **Dr. Peter Jarritt**, Deputy Director of the Brain Injury MedTech Co-operative
- **Ravi Chana**, Sector Specialist MedTech, Department for International Trade
- **Mita Brahmbhatt**, Programme Manager, Brain Injury MedTech Co-operative
- **Francesca Maria Piffer**, Programme Co-ordinator, Brain Injury MedTech Co-Operative

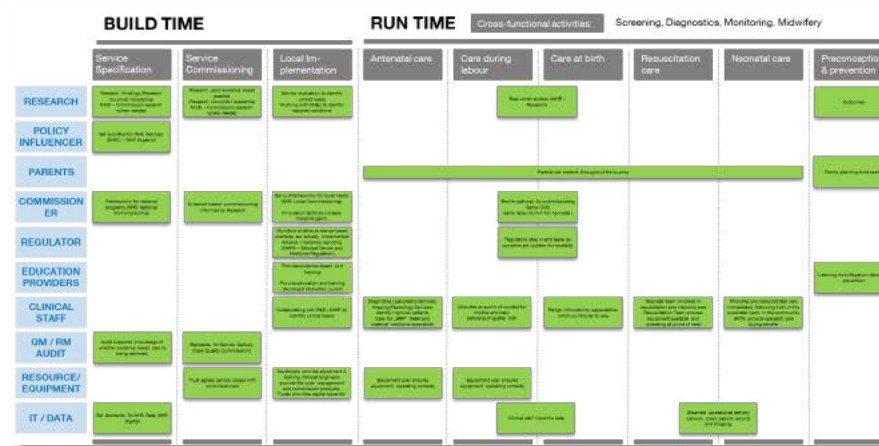
OVERVIEW OF STEPS OF THE WORKSHOP

1



Mapping of the ecosystem with all entities and organizations contributing to having “one healthy baby”

2



Assigning activities and capabilities to build time and run time phases on the ecosystem

3



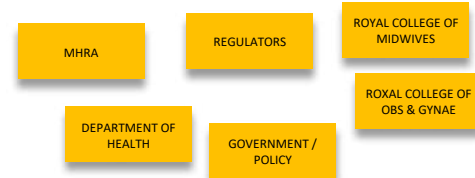
Discussion of findings based on alignment of capabilities and gaps thereof



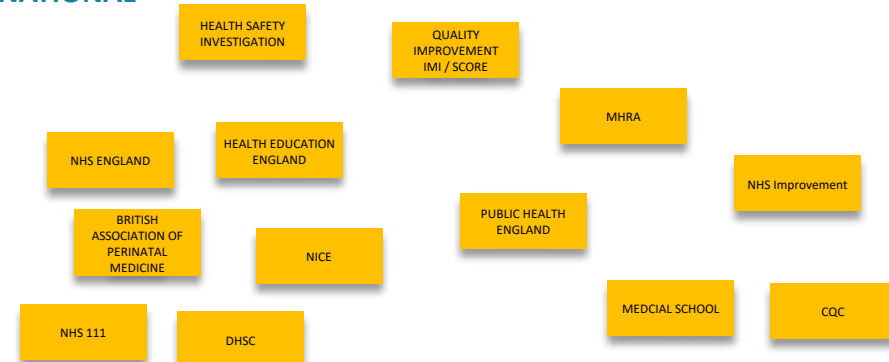
INFLUENCERS



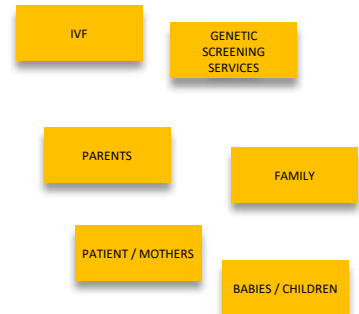
POLICY INFLUENCERS



NATIONAL



OTHER



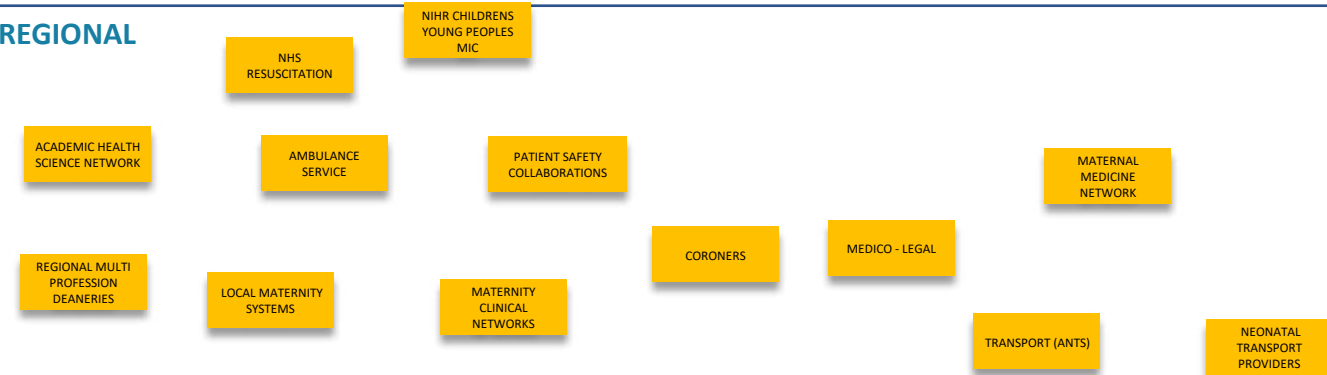
PHARMA



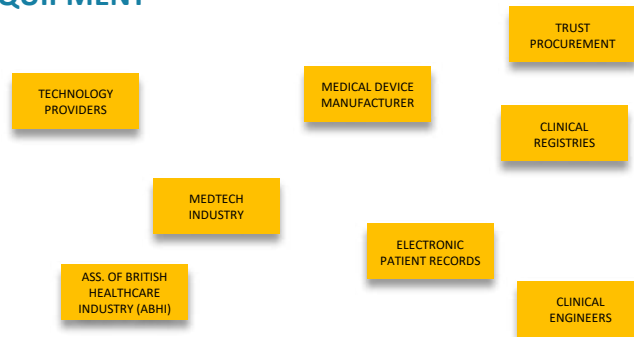
RESEARCH



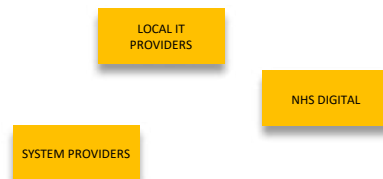
REGIONAL



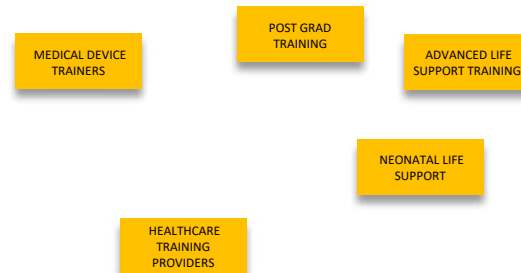
EQUIPMENT



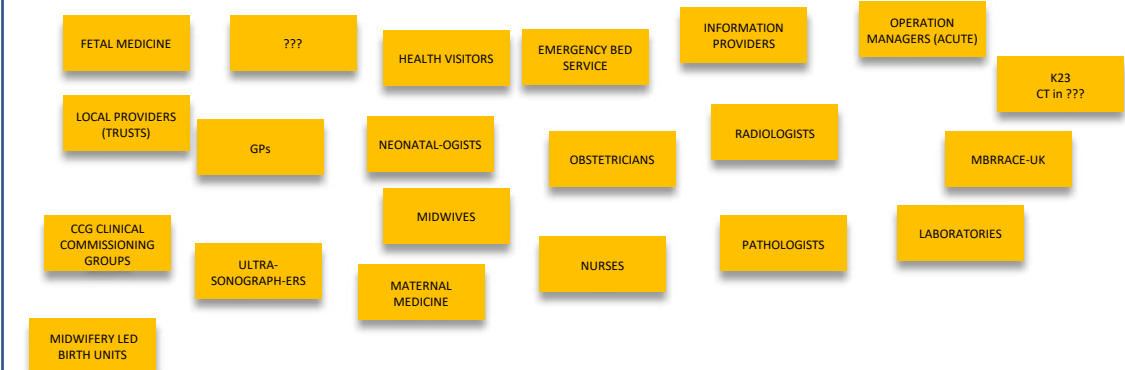
INFORMATION / PLATFORM



TRAINING



LOCAL HEALTHCARE PROVIDER



„ONE HEALTHY
BABY“

IN THE ECOSYSTEM, ACTIVITIES CAN BE DIFFERENTIATED IN A **BUILD TIME** AND A **RUN TIME**

BUILD TIME

Service Specification	Service Commissioning	Local Implementation
National Guidelines Development Research (MEDTECH + Clinical)	National and local commissioning	NHS Trusts Infrastructure Primary care capability Neonatal transport

Activities related to the **specification, build and commissioning**

RUN TIME

Cross-functional activities:

Screening, Diagnostics, Monitoring, Midwifery

Antenatal care	Care during labour	Care at birth	Resuscitation care	Neonatal care
...

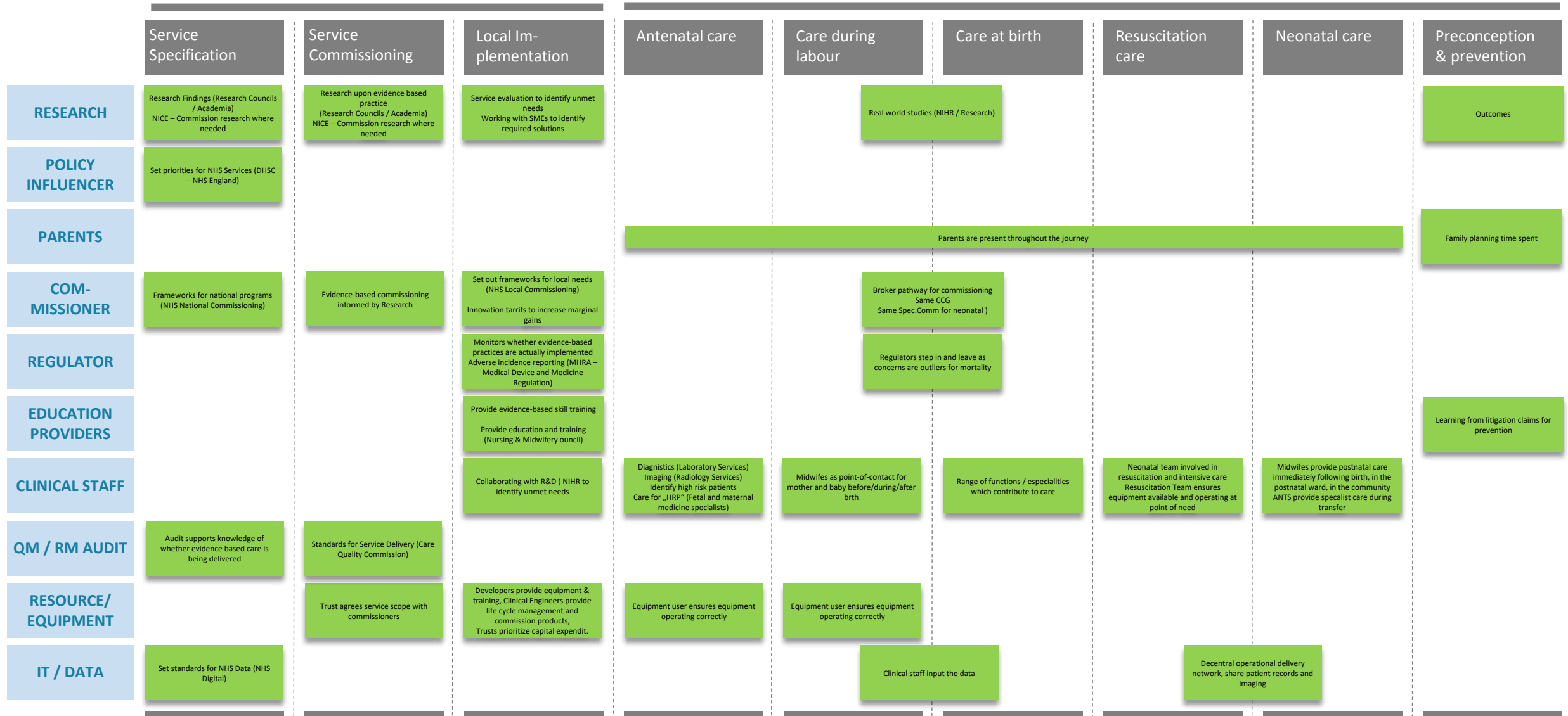
Activities concerned with the stable **operations and service delivery**

BUILD TIME

RUN TIME

Cross-functional activities:

Screening, Diagnostics, Monitoring, Midwifery



FOUR INITIAL AREAS FOR ACTION WERE IDENTIFIED

I

Introduction of post-market surveillance of clinical equipment

Data of equipment such as oxygen ventilators could be gathered by sensors, accumulated and analyzed in conjunction with data of patient safety issues. This could enable clinical staff to detect complications triggered by faulty equipment and help equipment providers to improve the safety and reliability of their products. Consent from parents is a precondition for the analysis of this data.

II

Drive development of the „antenatal fitbit“ that helps midwives in overseeing multiple patients

Midwives and other clinical staff have to oversee multiple patients during labor, lacking a „helicopter view“ on all patients and arising complications and high-risk situations. Having an overview from sensor data gathered from the mother could facilitate the detection of such complications and reduce overseeing issues during pregnancy.

III

Facilitate commissioning of MedTech products or data-driven services from startups

Startups with innovative solutions for maternity care are facing challenges when trying to sell their products and services to the NHS. They are confronted with the complexity of local commissioning. Programs for nationwide support of startups to commission services from them could help the founders to navigate the complexity and contribute to (marginal) gains in patient and child safety.

IV

Strengthen calls for specific needs of MedTech solutions on national level to trigger development of right products

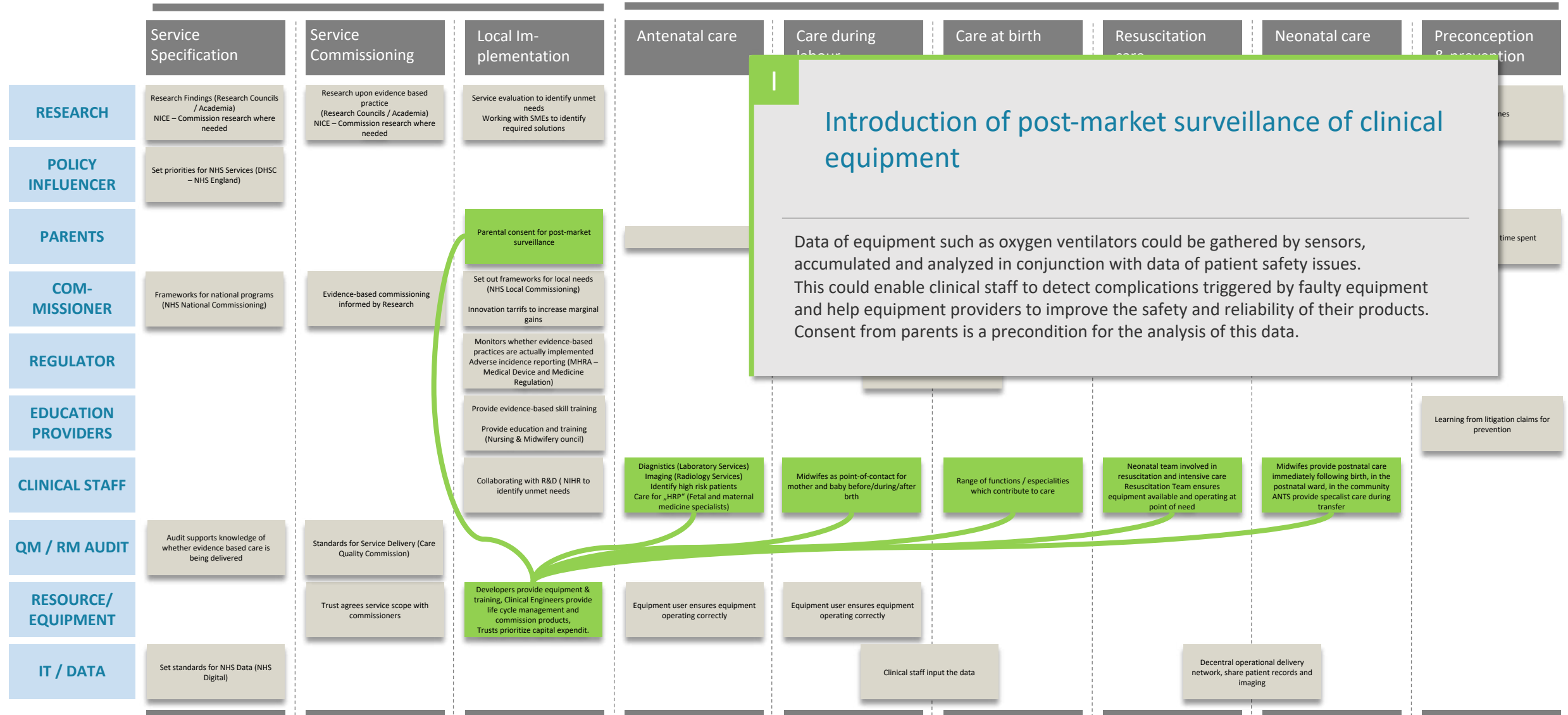
Innovations in MedTech are critical to realize marginal gains in patient and child safety. In order to direct innovators, developers and founders towards fields of applications where solutions are needed, communications from the national level could be promising. Through this, clear demand for specific services and products is declared.

BUILD TIME

RUN TIME

Cross-functional activities:

Screening, Diagnostics, Monitoring, Midwifery

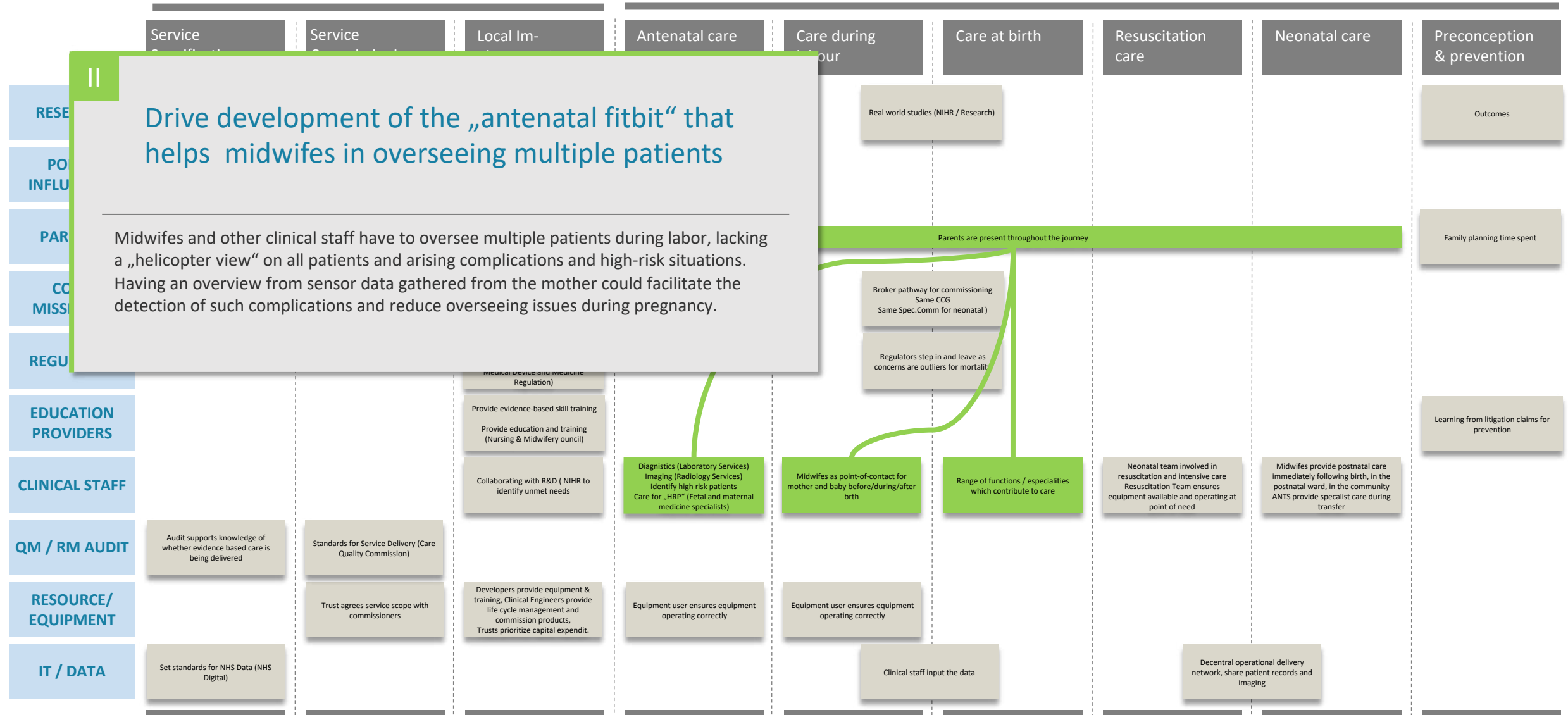


BUILD TIME

RUN TIME

Cross-functional activities:

Screening, Diagnostics, Monitoring, Midwifery

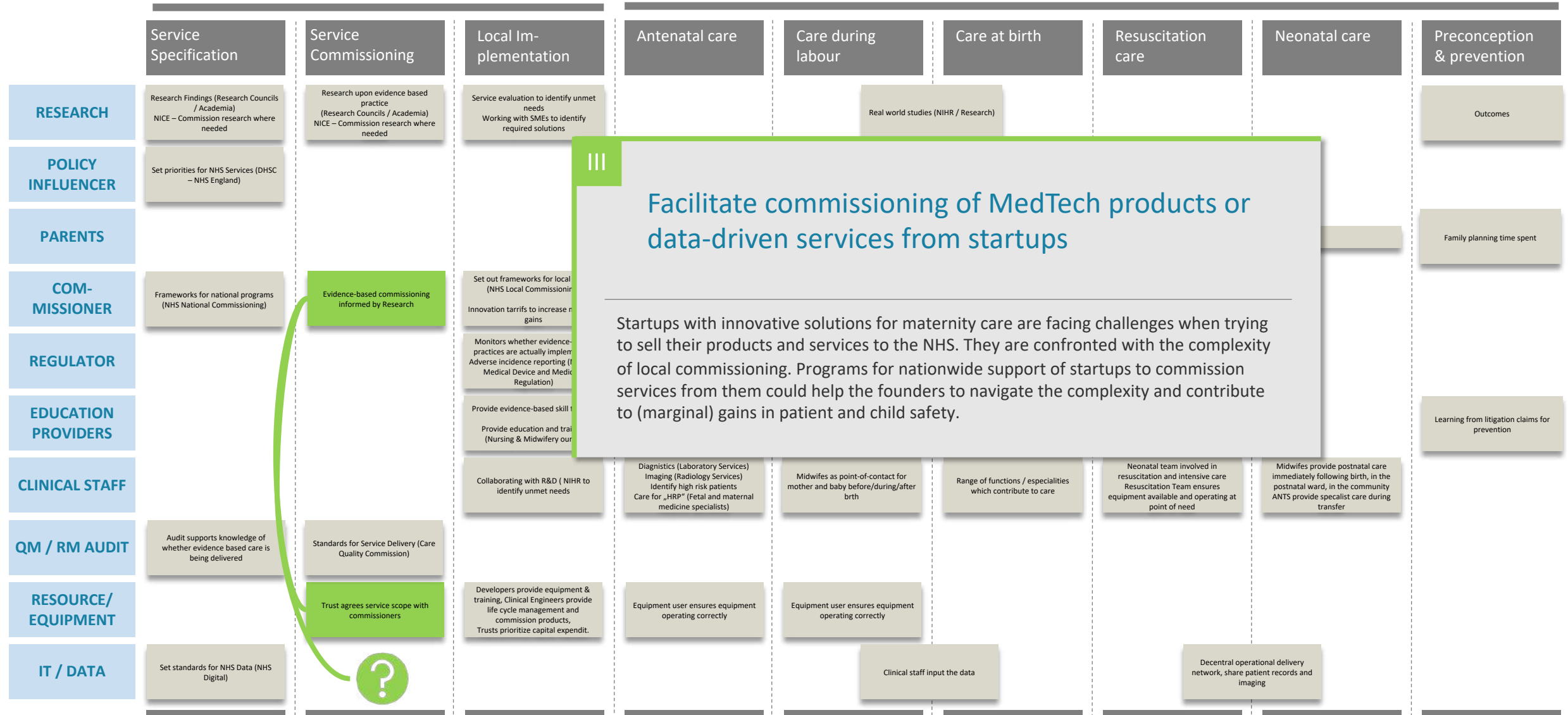


BUILD TIME

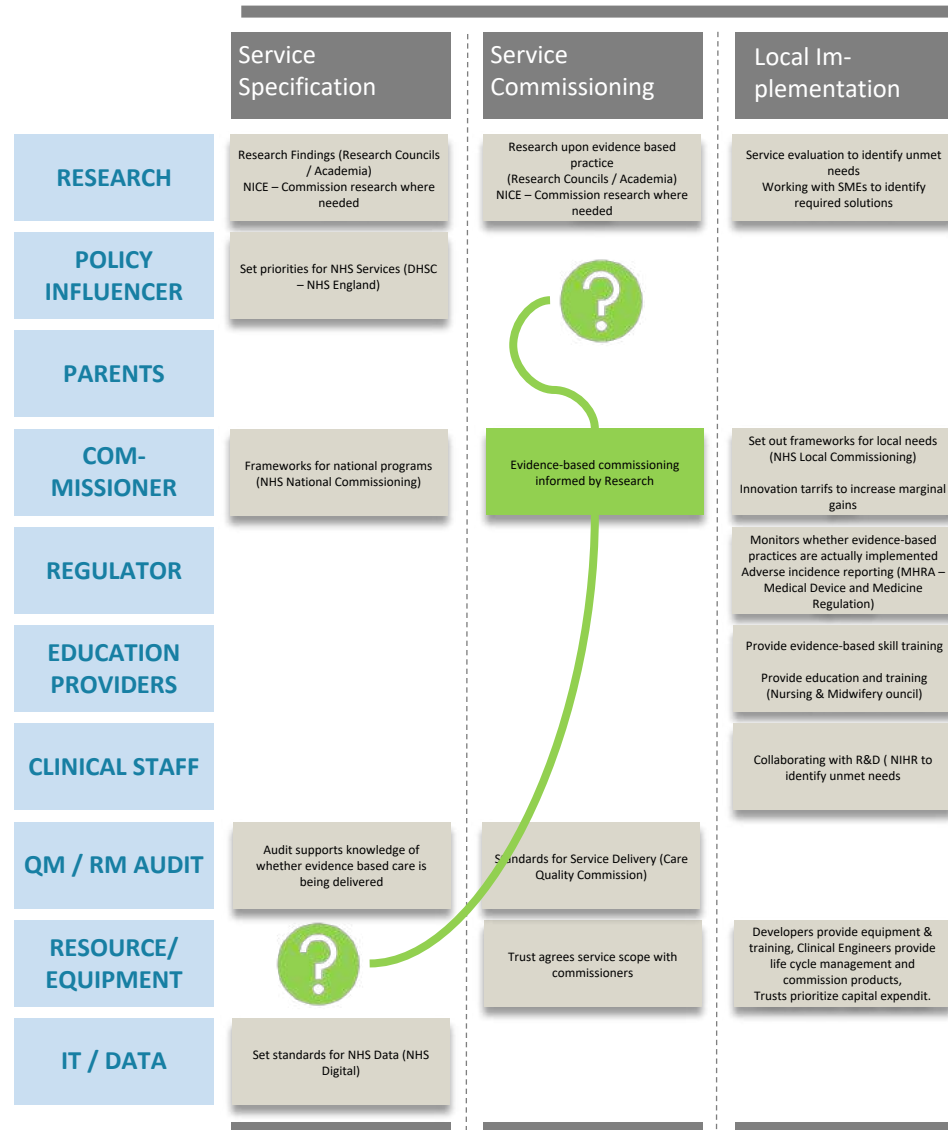
RUN TIME

Cross-functional activities:

Screening, Diagnostics, Monitoring, Midwifery



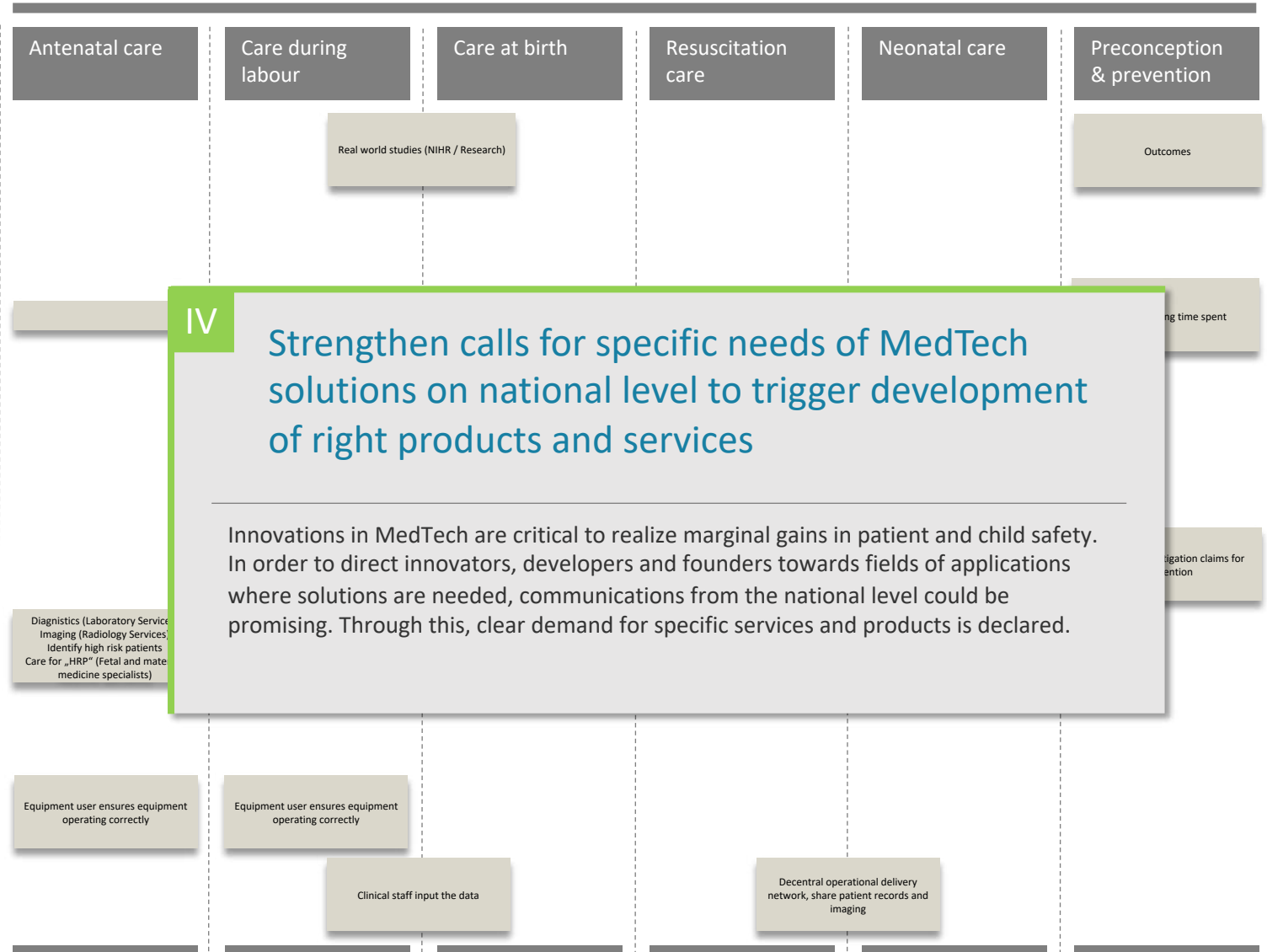
BUILD TIME



RUN TIME

Cross-functional activities:

Screening, Diagnostics, Monitoring, Midwifery





THANK YOU!