



Medicines & Healthcare products
Regulatory Agency

Board Meeting

Operational Transformation – October 2018 Update

22 October 2018

Issue/ Purpose:

To provide a progress update to the Agency Board on the Operational Transformation Programme

Summary:

The Agency Board reviewed the Operational Transformation Programme Business Case on the 24th September 2018 Agency Board.

This paper provides a brief update on the activity undertaken in the following 2 weeks since the OT Programme Business Case was reviewed. It primarily focuses on the governance and engagement activities that have now started.

Resource implications:

Transformation Division and cross-Agency resources are assigned to support the Operational Transformation Portfolio.

EU Referendum implications:

Yes

Timings:

Ongoing

Action required by Board:

To note

Links:

Author(s):

John Quinn, Director of Transformation and Chief Digital and Information Officer

Which of the five themes in the Corporate Plan 2013/2018 does the paper support?

All

If relevant, which Business Plan strategic activity does it support?

All

CET Sponsor(s): Jon Fundrey and John Quinn

A. ISSUE

1. To provide a progress update to the Agency Board on the Operational Transformation Programme.

B. PROGRESS UPDATE

2. The Agency Board reviewed the Operational Transformation Programme Business Case on the 24th September. Since then the primary focus has been on governance and engagement activities.

Governance

3. The Operational Transformation Programme Business Case was submitted to the Department of Health and Social Care for consideration and will be formally reviewed on the 15th November 2018.
4. The process includes the Business Case being uploaded to a portal, and for comments and questions to be provided from subject matter experts from Department of Health and Social Care on the case. The Agency then responds to the points raised and makes adaptations to the case in advance of the Department of Health and Social Care Investment Committee meeting.
5. Jon Fundrey and John Quinn met with representatives from the Department of Health and Social Care review team to present a high-level view of the case and to receive immediate questions of clarification. The case was well received, and questions are now beginning to flow through from the review team.
6. Early comments include the reordering of content between sections to improve readability; gaining further understanding of the costs and benefits at a detailed level; and understanding our options around transformation.
7. The Investment Board also considered a draft set of prioritisation criteria and weightings that have been established by the Enterprise Portfolio Management Office of Transformation Division. These criteria will now be used and refined when considering individual project business cases.

Engagement

8. Engagement has been a high priority for this programme, recognising the importance of staff engagement in its successful delivery. We entered a new phase of engagement in May when the programme was divided into seven workstreams. We agreed an overarching strategy for engagement, identifying three key audiences (senior leaders, workstream teams and all staff) and objectives (to commit, to buy-in and to understand). We developed strong graphics to help tell our story and make the case for change and then identified tactics and channels to deliver our objectives to these audiences.
9. Building on this, we have offered a range of information in various channels to staff:
 - workstream open sessions and sponsor blogs;
 - informal open sessions on a range of transformation topics and transformation blogs;

- INsite content
 - presentations at divisional meetings; and
 - presentations on Operational Transformation at staff inductions.
10. We ran a pulse survey in July to gauge levels of understanding and change readiness across the organisation. The results were published on INsite and used as the basis for a discussion session at the Managers' Conference. This feedback continues to inform our future plans.
 11. Operational Transformation has also been a key agenda item at all our set-piece staff engagement events: the Managers' Conference (6 September), All Staff Meetings (27 September – 2 October) and the Senior Leadership Group (10 October). Key messages in the build-up to publishing the business case have been around inspiring people about the exciting opportunities going forward, managing staff expectations about what is in the case as well as letting them know when and how they will have access to it.
 12. On Thursday 11 October, we published the Operational Transformation Programme Business Case on the Agency intranet with a news article setting out key messages about financial sustainability, the overall focus and ambition and how the case has been developed. There was also refreshed content published on each workstream as well as information about a live staff event and future engagement opportunities. The overarching message has been that we want to support staff in interpreting the business case and identifying the relevant content for them.
 13. We are holding a Transformation LIVE event on 16 October connecting 40 staff in one room and 70+ each in two other rooms in London and South Mimms and 1,000 licences for staff to join the event as a live webinar from their laptops. This event will be hosted by the CEO with a CET panel available to answer questions.
 14. Following the live event, there will be another round of workstream open sessions, presentations at divisional meetings and a series of *My Story* pieces on INsite which will bring to life some of the initiatives now underway from the perspective of those delivering them.
 15. The next step is to develop a detailed plan for external engagement with key stakeholders, keeping them informed of the progress of the programme and clearly communicating what it means for them.

Workstreams

16. Supported by the Transformation Division the 7 workstreams have started to progress the 95 change proposals identified within tranche 1 of the Programme Business Case through early, high-level stages of analysis to produce project briefs.
17. These briefs are the start of the internal governance process and are used to further identify ownership, scope resourcing requirements and confirm benefits and next steps for delivery. These will then be submitted to the Investment Committee to determine which ones will be prioritised to move forward.
18. Workstream sponsors have identified leads within the operating divisions to own and progress the change proposals. Around 100 staff across the

workstreams and operating divisions are engaged in this activity supported by the Transformation Division.

19. Fortnightly sessions with the change proposal owners and sponsor are being held to monitor and track progress and digital collaboration areas have been setup for each workstream to help coordinate and share information and progress.
20. Individual workstreams are focusing on their priority areas:
 - **OT.01 | Design and Enable**
Concentrating on two priority areas: the high-level design off the Agency's operating model in each of the Brexit scenarios; and the building of internal capability to deliver and cope with change. Upcoming activities include managing reactions to change training and "lunch and learn" sessions.
 - **OT.02 | Customers**
Initial work has started on the change proposals on business development and marketing consolidation across the Agency and multi-channel access with a number of cross-Agency workshops held.
 - **OT.03 | Authorisations**
Project briefs have been drafted across 10 change proposals within tranche 1 and are being further developed with change leads. Focus areas include simplifying the assessment process; enabling staff to be able to work outside of therapeutic or regulatory areas to increase flexibility; and
 - **OT.04 | Science and Research**
Workstream leads are in the process of being identified and project briefs are being developed around the following areas: increased utilisation for resources; improving the way we use our facilities such as laboratories, equipment, cold storage and consumables; and generating new income opportunities.
 - **OT.05 | Safety and Surveillance**
Workstream leads have been identified and are progressing multiple change proposals including developing a risk proportionate approach for Risk Management Plans (RMP) for generic products and Patient Safety Update Reports (PSURs); and reviewing ways to monetise the safety reporting app that has been developed.
 - **OT.06 | Assurance**
Activity has focused on the change proposals covering development of further symposia events around the GXP disciplines to meet customer demand; around streamlining the inspection process; and seeking opportunities to increase the range of inspection services offered to increase revenue.
 - **OT.07 | Corporate**
Discovery has started around the corporate service operating models and reviewing 10SC capacity. Work has already started on reducing IT operating costs through consolidating service contracts and retendering.

C. NEXT STEPS

21. Continue to progress the case through the DHSC governance process for the 15th November
22. Continue to progress individual change proposals through the internal governance process
23. Continue a wide-scale programme of staff engagement

Appendix:

A1 - News piece to publish the case to all staff

A2 - Intranet content to publicise business case staff event

A-3 Refreshed content on Operational Transformation to support publication of the business case

A-5 Content to publicise workstream open sessions

A-6 Example Digital Collaboration Area

A1 - News piece to publish the case to all staff

A blueprint for change – Operational Transformation business case sets out phase one change plans

Published on 11 October 2018

Today, we are publishing our [Operational Transformation Programme Business Case](#) to all staff. **The Programme Business Case remains Official Sensitive so is not suitable for circulation outside the Agency.**

Our Board and CET have approved this case which sets out detailed plans for the next phase of the programme.

Operational Transformation is the Agency's proactive response to the impact of Brexit scenarios on our financial position; the need for investment in change to enable improved efficiency and productivity; the need to replace our ageing IT systems; and changing customer needs.

The Programme Business Case has been written for the Department of Health and Social Care (DHSC) Investment Committee to get approval for the overall investment needed and to draw down funding for the first phase of work. The overall cost required to deliver the full programme is estimated to be £80.95m or £83.52m in a continuing IP Brexit scenario. The first phase of work requires an investment of £7.06m.

Financial sustainability

The Programme Business Case identifies approved initiatives under each of the Operational Transformation workstreams which are getting underway in the first phase of work. These are all initiatives which need to go ahead regardless of the final Brexit outcome, which require relatively low short-term investment, will reduce operating costs or generate income in the short term, or are critical to supporting the Agency's public health mission. These initiatives are what will bring OT to life for many colleagues as they will start to bring about meaningful change in your areas of work. You can [read more about each workstream on the OT pages on INsite](#).

For the first time, the Agency has brought together all the information necessary to show how the Agency needs to change to be financially sustainable over the next five years. Until now, the cost of investing in new systems and processes outweighed the available funding – this Programme Business Case brings together our financial model for reducing costs, increasing efficiencies and maximising income-generating opportunities.

Focus and ambition

This first phase – from now until mid-2019 – focusses our efforts on preparation for the four Brexit scenarios, revenue growth and savings, extending the life of our ageing IT systems and building capabilities within the Agency.

In preparing this Programme Business Case, we have been careful to recognise that review points will be necessary throughout the five-year life of the programme to allow for changing circumstances. This means that our transformation will build momentum over time and is deliberately positioned to respond to an uncertain future.

The aim of the Programme Business Case is to set out the direction of travel and give a clear focus on what we need to deliver over the next nine months. The Programme Business Case does not set out detailed plans for the future for the next five years, nor does it provide details about possible headcount reductions or structural changes within the organisation at this stage. The final decision about the longer-term direction can only be taken after we know the final outcome of Brexit.

What it does is make clear our ambition:

- we will put customers at the centre of what we do, enhance their experience and improve our customer insight;
- we will achieve greater ease and agility in licensing of safe and effective medicines;
- we will ensure that research capabilities, scientific expertise and Agency-wide investments are focused to create the maximum impact on public health while maintaining scientific capability;
- we will improve the Agency's ability to proactively monitor and act on safety insights across the product full-lifecycle through joined-up systems, processes and data;
- we will enhance our ability to perform risk-based approaches, holding regulated parties to account, ultimately ensuring public health through a safe global supply chain; and
- we will have standardised and simplified corporate services across all three centres.

Case development

This Programme Business Case has been delivered by workstream sponsors with a core group, subject matter experts and reviewers from across all divisions and centres driving the work forward; around 90 people have been involved. This work has been supported by Transformation Division and approved by CET. Each In addition, over 30 engagement events have been held in the last six months, reaching hundreds of staff through open sessions,

divisional meetings, blogs, INsite content, Senior Leadership Group and Mangers' Conference presentations.

The Programme Business Case has now been submitted to the DHSC Investment Committee, following approval from both our Board and CET. We are having ongoing dialogue with the committee and expecting their decision in November. In the meantime, we will continue to work on the initiatives outlined in the first phase.

Engagement

On 16 October, the Transformation LIVE event will give staff the opportunity to discuss the business case at both 10 South Colonnade and South Mimms with the ability to access the event remotely via laptops for those unable to attend in person.

[More information is available on INsite](#). Participants can submit questions via Sli.do which will be put to CET members. For those unable to access the event live, a recording of the event will be available to everyone via a link on INsite.

A2 - Intranet content to publicise business case staff event



Staff event: Transformation LIVE – what the OT business case means for us

Published on 11 October 2018

The Chief Executive, Ian Hudson is chairing a staff event on Tuesday 16 October, between 10-11am, alongside a panel of Directors and others to answer questions on what the [Operational Transformation Business Case](#) means for us, our teams and the Agency as a whole.

We have made this event as accessible to as many staff as possible via a number of channels. The live event will **start promptly** at 10am, so if you are coming along to one of the three rooms below, **please arrive before the start time**. You will need to look at the business case ahead of the event and come prepared with questions to ask.

If you are attending the event in a meeting room please **do not** join the webinar from your laptop, as this may disrupt the session, but you can use your laptop to ask questions via Sli.do.

The information below outlines how you can take part and the format for the event.

Access to the event via ...	Attendees	Channel for questions
The Bridge, Ground Floor, 10SC	<p>x40 attendees from all divisions (invite only)</p> <p>Chair: Ian Hudson</p> <p>Panel: Jon Fundrey, John Quinn, Vanessa Birchall-Scott, Rachel Bosworth and</p>	<p>Raise questions in the room</p> <p>OR</p> <p>Via Sli.do</p>

	representatives from the workstreams	
Large Meeting Room, South Mimms	x70 attendees from all divisions (invite only – confirmation coming this week) Facilitator: Marie Donatantonio	Raise questions in the room OR Via Sli.do
Round Room, 10SC	x75 places available in the room on a first come, first served basis Facilitator: Ben Scott	Raise questions in the room OR Via Sli.do
Live streaming to your laptop/ PC via Zoom	x1,000 licenses	All those accessing the event via Zoom will be set to mute by default to minimise background noise, so questions should be submitted via Sli.do To join the Webinar click on the link: https://mhra.zoom.us/j/664501943 See below for further information on how to join by audio only.
Link to a recording of the event via a link on INsite <i>after</i> the event	All staff	There will be no facility for questions – if you have a question after watching the recording, please contact senior leaders from your division.

How will I know if I've been invited?

Invites have been sent this week to all those selected to attend the event in The Bridge. Invites will be sent to those attending in the Large Meeting Room shortly.

How have the invites been sorted out?

Directors were asked to nominate people from their divisions to attend in The Bridge – the room size means the numbers are very limited which is why we are making sure there are other ways to participate in the event.

How do I access Zoom?

zoom



Just click on the Zoom join link and follow the instructions. This document explains [how to set-up Zoom](#) so you get the best experience on the day. **Please do this ahead of the event itself on Tuesday to ensure you are able to access Zoom.**

To join the Webinar	https://mhra.zoom.us/j/664501943
Join by Telephone (audio only)	For higher quality, dial a number based on your current location.
Dial:	United Kingdom: +44 (0) 20 3695 0088 or +44 (0) 20 3051 2874 or +44 (0) 80 0031 5717 (Toll Free)
Webinar ID:	Webinar ID: 664 501 943
International numbers available:	https://zoom.us/u/azDLDDD4d

If you are going to listen to this live via Zoom don't forget your **headphones** or perhaps book a meeting room with some colleagues and view the event together around a single screen.


If you have any problems accessing Zoom, please contact: IT helpdesk





How do I use Sli.do?

Sli.do is a free web service and can be accessed via an app on your phone or via the [internet](#). The event code is #OTBC you enter the code and you will be able to type your question. These questions then come through to an administrator in the Bridge who will ensure the questions appear on a screen in front of Ian who will put questions to the panel.

A-3 Refreshed content on Operational Transformation to support publication of the business case



Working for us - [Corporate information](#) - [Buildings and facilities](#) - [External relations](#) - [Your IT](#) - [Policies and procedures](#) - [Resources](#)

Operational Transformation

OT.01

OT.02

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Previous work

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Operational Transformation

Welcome

The world in which we operate is changing – the Operational Transformation (OT) is the Agency’s proactive response to the impact of Brexit scenarios on our financial position, the need for investment in change to enable improved efficiency and productivity; the need to replace our ageing IT systems; and changing customer needs. This diagram explains the [need for change](#).

The OT programme is split into seven workstreams representing the different ‘services’ we offer, each led by a CET sponsor. Each workstream contains multiple projects to help it deliver its objectives.


We want to transform the Agency to meet the demands of our customers in the future, we want to continue to be a world-leading regulatory organisation and establish new relationships and new ways of working to continue our mission to protect public health.

Blog

This space will be used to publish brief, informal and personal updates on what’s happening around Operational Transformation. We hope to publish content here once every couple of weeks so keep visiting the page to check for new items.

OT | Programme Business Case – 03.10.18

Many colleagues will have recently attended either an All Staff Meeting or the Managers’ Conference and heard that the Operational Transformation Programme Business Case has recently been submitted to the DNSC Investment Committee awaiting approval from CET and the Agency Board.



A-5 Content to publicise workstream open sessions

Find out the latest news from each of the OT | workstreams – open sessions for all staff

Published on 11 October 2018

Starting on Wednesday 17 October, we will be running another series of OT workstream open sessions.

With the recent publication of the [Operational Transformation \(OT\) Programme Business Case \(PBC\)](#), you may have questions and want more clarity on the OT workstreams, what they mean for you, your team and the wider Agency.

Each workstream has a CET sponsor, and they will be on hand to answer your questions and give an update on the area they are leading on.

Come along and find out:

- what’s happening with the workstream;
- what projects are currently being delivered;
- what are the next steps; and

how you OT workstream	CET sponsor/s	Details of session
<p>OT.04 Science and Research and</p> <p>OT.06 Assurance</p>	<p>Christian Schneider and Sam Atkinson</p>	<p>Wednesday 17 October</p> <p>The Large Meeting Room,</p> <p>NIBSC</p> <p>2 to 3pm</p>

OT.04 Science and Research and OT.06 Assurance workstreams – open session for all staff	Christian Schneider and Sam Atkinson	Wednesday 17 October The Large Meeting Room, NIBSC 2 to 3pm
OT.03 Authorisations workstream open session for all staff	Siu Ping Lam	Thursday 18 October The Bridge, Ground Floor, 10SC 10 to 11am
OT.07 Corporate workstream open session for all staff	John Wilkinson	Friday 26 October The Games Room, NIBSC 10 to 11am
OT.07 Corporate workstream open session for all staff	John Wilkinson	Tuesday 30 October The Bridge, Ground Floor, 10SC 10 to 11am
OT.02 Customers workstream open session for all staff	Rachel Bosworth	Thursday 1 November The Large Meeting Room, NIBSC 11 to noon
OT.04 Science and Research workstream – open session for staff	Christian Schneider	Wednesday 7 November The Bridge, Ground floor, 10SC 2 to 3pm
OT.05 Safety and surveillance open session for staff	June Raine	Tuesday 13 November The Bridge, Ground floor, 10SC 11 to noon

The screenshot shows a SharePoint site interface for 'OT.02 Customers'. At the top, there is a navigation bar with 'Office 365' and 'SharePoint' logos, and a secondary navigation bar with links to various site sections: Home, OT.01 Design and Enable, OT.02 Customers, OT.03 Architecture, OT.04 Science and Research, OT.05 Safety and Surveillance, OT.06 Assurance, and OT.07 Corporate. The main header area includes a search bar, a 'New' button, and a 'Published 01/10/2018' date with an 'Edit' button. The left sidebar contains a navigation menu with categories like Home, Agency Documents, Team Documents, Restricted Documents, Discussion Board, Project Briefs, Notebook, Pages, Site contents, Recycle bin, and Edit. The main content area features a large title 'OT.02 Customers' with a description: 'Maximising effectiveness of customer experiences across all channels, improving customer insight and service promotion and enhancing targeted customer engagement, education and business development capability'. Below this is a link to contact the site content owner, Stuart Hetherington. The 'Activity' section displays two recent documents: 'CUSTOMERS-Change_proposals-OUTPUTS-for_Review.pptx' by Sarah, Susan (uploaded 10 minutes ago) and '2.0-Service-Process-Mapping-v0-2.xlsx' by Steven, Jon (uploaded 9 minutes ago). The 'Upcoming events' section lists two events: 'OT.02 | Customers - Open Session @ 10SC' on Wed 31 Oct, 1400, and 'OT.02 | Customers - Open Session @ South Mirra' on Thu 1 Nov, 1100. A 'Feedback' button is located at the bottom right of the page.