Appendix 1

Russland NHS Foundation Trust

Business Case

Business Area		**Author & Project Lead**		**Project sponsor**	
Business case number		**Project name**		**Submission date**	

1. Outline business case or further iteration	Indicate here if this is the first version of this business case or a further iteration on the basis of previous guidance/feedback from the Executive Management Group (EMG) / Board. Give date of previous iteration. This is the first version of the business case for repetitive Transcranial Magnetic Stimulation (TMS) for the Russland NHS Foundation Trust. **Project aim** The aim of this project is to provide an enhanced TMS service for an initial pilot period of 24 months to secondary and tertiary care mental health service users in the region served by the Integrated Care System. At the end of this interim, period a further business case will be submitted for a permanent service with an income generating element to support the service provision. **Business case summary** TMS is an innovative and clinically effective treatment for difficult to treat depression (DTD), resulting in remission and the substantial reduction in symptoms of depression. It is recommended by NICE. The current TMS service, based on one TMS machine that is nearing the end of its lifespan, is provided mostly on a 'goodwill' basis as there is no

	allocated budget for its provision. It treats 2 people each month. An enhanced service would be based on two TMS machines. It is well established that TMS treatment is cost-effective. In the Russland Trust, its cost-effectiveness would be enhanced in three principal ways: • providing treatment to Trust staff absent with depression/ anxiety • generating income of £60-96,000 per annum treating one self-funder each month from private provision. and, • reducing service users' utilisation of mental health services post-TMS treatment. These cost-effective dimensions would reduce financial pressures on the Trust.
2. What is the case for this change? What do you want to do and why?	Explain the context of the proposed business change, detailing any particular pressures, new funding streams, commissioner or legislative/regulatory requirements etc. Also include strategic drivers for the change and alignment with the Trust's Strategy. Set out your preferred option. Note here whether or not this business change was set out in the Annual Plan for the business area. The business change advocated in this proposal was not set out in the Annual Plan for the business area. **What is TMS treatment** Repetitive Transcranial Magnetic Stimulation (TMS) is a non-invasive technique used in the treatment of depression. **Why does the Trust need a TMS Service** The reasons set out below, do not address the reasons of reducing financial pressures on the Trust and income generation to support service development and provision, which are considered later. <u>1. NICE recommendation and Royal College of Psychiatrists position</u>

TMS is recommended by NICE as a treatment for depression (NICE, 2015). To align itself to the decade old recommendation, TRUST should providing TMS.

In 2017, the Royal College of Psychiatrists issued a position statement in which they stated: 'Over the last decade TMS has been used widely for the treatment of depression and is now an established safe and effective treatment option for depression and treatment resistant depression' (Royal College of Psychiatrists 2017).

2.Clinically effective

- In 2022, in a Random Controlled Trial, participants experiencing difficult to treat depression were randomised to treatment with TMS or to a switch of antidepressants, both in combination with psychotherapy. TMS resulted in a significantly larger reduction in depressive symptoms than medication. The outcomes were reflected in a higher response (37.5% v 14.6%) and remission rates (27.1% v 4.9%) for those participants in the TMS arm of the trial (Dalhuisen, et al 2024). This would indicate that TMS is a strong candidate for the next step in the treatment pathway for people who are not responding to antidepressants.

- In 2023, in a large systematic Random Controlled Trial, 250 participants were randomly assigned to 20 sessions over 4-6 weeks of either connectivity-guided intermittent theta burst neurostimulation (cgiTBS) or TMS. The participants had not responded to two previous antidepressant treatment attempts and had been ill for an average of 7 years.
    - Persistent decreases in depressive symptoms were seen over 6 months, with no differences in the primary outcome between the different neurostimulation treatment arms. TRUST was one of the research trial centres.

- The study showed a good effect from the treatment:
  - more than 66% received a positive response from the treatment
  - 33% showed substantial improvements in the severity of their depression, anxiety and thinking, with better function and quality of life over this period
  - 50% experienced improvements sustained over 26 weeks
  - 20% of the participants moved into remission and sustained this (BRIGhTMIND study, 2024).

- In the Trust's TMS service, the preliminary evidence for 33 people who received 20 sessions of TMS show a significant response and remission rate for DTD. For:
  - Severe depression:
    - 24% of service users achieved remission
    - 24% of service users experienced a reduction in the symptoms from moderate/ severe depression to mild depression
    - Overall 51% demonstrated a response to treatment (defined as 50% reduction in pre-treatment QIDS-SR to treatment 20 QIDS-SR).
    - the effect size was 1.15, indicating a very large effect size from the treatment.'
  - Anxiety:
    - 23% of service users experienced remission
    - 9% of service users experienced a reduction in their anxiety to mild anxiety
    - Overall. 42% patient's demonstrated response to treatment (defined as 50% reduction in pre-treatment GAD-7 to treatment 20 GAD-7).The effect size was 1.20, which also is a very large effect size.

3. Well tolerated and safe treatment

- TMS is well tolerated by service users (Slotema, C. et al, I (2010).
- It has a good safety profile (BRIGhTMIND Study, 2024 and NICE, 2015).
- Service users can access TMS treatment minimal disruption to their daily life. For example, they can return to their usual activities after a treatment session, which is in contrast to ECT.
- The Team delivering TMS report that non-attendance at appointments is infrequent.

4.Patient choice

People experiencing the distressing condition of DTD currently have limited treatment choice: either augmented antidepressant treatment; or Electroconvulsive treatment (ECT). Offering TMS would enhance treatment choice.

In England, around 1:7 NHS Mental Health Trusts in England are offering TMS. In the region, The Long Valley NHS Trust have a TMS service and now neighbouring Mental Health (MH) Trusts of Cam and Lune Partnership MH Trust and the Sedge and South Hemp MH Trust are looking at developing their own TMS services. On the basis they proceed, our Trust will be one of the few Trusts in the region of the country that does offer service users this treatment choice.

TMS is simpler and safer to deliver than ECT:

- it is not associated with cognitive deficits. (Sharbafshaar, M (2023)
- it can be used with service users with significant physical health difficulties for whom receiving a general anaesthetic poses a significant health risk
- it does not carry the treatment burdens associated with ECT, such as:
    - an anaesthetic and related consultation

- a delay to driving post-treatment
- the requirement for someone to be with the service user overnight, post-treatment
- a service user living alone in the community would require in-patient overnight care following ECT treatment, increasing the financial cost of treatment
- the social stigma associated with ECT

5. Diversity of interventions

Depression is a well-established risk factor for self-harm and suicide.

The region's Suicide and Self-harm Preventive Research Collaborative (Health Innovation Partners, 2025) reports that the preventative approach requires access to 'more diverse interventions' for mental health problems. TMS extends intervention diversity available to service users experiencing depression and at risk of self-harm and suicide.

6. Reduction in service utilisation

Preliminary data from Clinical Record Interactive Service (CRIS) indicates that TMS might aid a reduction in the utilisation of the following secondary care mental health services. There were significant reductions in the areas of crisis service contacts and inpatient admissions

- Crisis contacts: there was a 70.69% reduction
- Inpatient admissions: there was a 90% reduction in admissions and the average number of days of admission fell from 202 days per annum to 19 days per annum.

- Data were not available for the impact of TMS on the provision of ECT. However, this type of service reduction was reported by Redburgh Mental Health NHS Foundation Trust. In their formal TMS Service Evaluation, service utilisation decreased in the areas of: psychiatric inpatient bed; ECT; multiple different medications; and, intensive psychological therapies to 'a low level'.

- A reduction in service utilisation would reduce the financial pressures on the Trust. The interim enhancement of the TMS service of 24 months, would enable more data to be gathered in relation to the preliminary findings.

<u>7.Reducing staff absence days linked to depression/ anxiety</u>

- In the BRIGhTMIND Study, participants demonstrated clinically important improvements in functioning (signified by a 6.5 point decrease in impairment of functioning using the Work and Social Adjustment Scale (WSAS). The WSAS evaluation of Russland Trust's TMS service users shows a similar improvement in functioning at 5.15 points.
- The Trust aims to reduce staff absences by 1%. In the Trust, stress/ anxiety/ depression/ other psychiatric condition is the largest reason for staff absence.
- From April 2025 a referral interface has been established between TMS service and the Well-being Hub. Each month, the Hub receives 20 Trust self-referrals citing the reason of depression for the referral. Information to support staff elect TMS is in process eg a video including a staff member who has benefitted from TMS treatment.
- Examples of indicative costs-savings from TMS treatment:
    - If a Band 5 member of staff was absent for 200 days and experienced successful TMS treatment by day 43 of their absence (ie shortest possible pathway), then the direct cost savings would be £24,261.21
    - If the Band 5 member of staff was absent for 200 days and experienced a longer delay to successful treatment (ie 111 days), the direct cost savings would be £13,753.17
    - The cost savings for a Band 7 in the same scenarios would be: £36,800.80 and £20,861.60, respectively.
- These costs savings are in addition to the following:

- A reduction in the HR and management costs of supporting the staff absence
- A reduction in the cost of employing an agency worker as 'backfill'
- A reduction in the stress and pressure on the team from a staff member returning early
- An earlier return to the full activity of the team
- An improvement in patient care by having a full team
- An improvement in the staff member's well-being

8.Income generation to support the Trust's NHS provision of TMS

The model of private income supporting the delivery of NHS TMS treatment provision is an established model.

In the initial enhancement of the service there would be scope to develop the service to generate income from the following streams set out below.

- private self-funding (£5-8,000 c. per course of treatment).
- If the service provided TMS treatment to only one self-funding individual each month it could generate an income of between: £60,000 - £96,000 per annum.
- in 2017 Redburgh had a private TMS clinic for corporate clients, and self-funding individuals. TMS was provided alongside a range of occupational health interventions. They delivered TMS treatment to 1-2 people each month; staffing issues was a factor in its closure. One of the closest private clinics to this region reported that they have provided treatment to people who have travelled from other regions of the country. Currently the Trust footprint is a 'desert' for private provision.
- providing TMS services to service users from other locality Trusts in the region. Over a four-year period there have been 16 requests for TMS treatment. We have been advised that any formal agreements in relation to the provision of ECT would not be applicable to TMS.

There are other income streams that could be explore in any future enhancement of the service:

- seeking an arrangement with private provider/s of TMS to provide treatment to their customers resident in the region, generating an income of around £5-8,000 c. per course of treatment. There does not appear to be a private provider in the region. Having spoken with a private provider in the South West, they reported that they have people travelling from Norwich, the Lake District and London to receive treatment.
- scope the potential for taking advantage of the market in Mental Health (MH) Tourism. The presence of the cultural heritage in the Trust footprint would be a 'pull' for such health tourists. Outside of London, one Trust is setting up its TMS service geared to providing treatment to the MH tourism market
- charging Acute Trusts for treating their chronic pain and rheumatology patients who are experiencing a major depressive disorder as a result of their primary condition
- making an application to the Integrated Care Board for investment funding to become the TMS Hub for the region. This would negate the need for negotiating Service level Agreements with locality Trusts in the ICB area. TMS has been provided to 20 service users from other locality Trusts. This provision has to-date been provided free of charge.

<u>10. TMS is a cost-effective treatment</u>

For the purpose of this proposal, the cost-effectiveness studies identified in relation to TMS have been presented in 3 categories:

- Cost-effectiveness comparing TMS with antidepressant treatment/ Treatment as Usual (TAU).
- TMS relative to ECT
- TMS as a treatment for Bi-polar depression

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11.Reduction in waiting lists

- in the Trust's waiting list for TMS treatment has ranged from 2-9 months. In May 2025 it was 9 months. An enhanced service would address this waiting list.
- If is not possible to predict its impact on waiting lists in secondary care because the service until now has had a very limited capacity. The preliminary findings of CRIS indicate that there is likely to be a reduction in service utilisation, which could have an impact on waiting lists.

12.Next generation of innovative, personalised mental health treatments

- The proposal enables the Trust to be at the vanguard of delivering the NHS' next generation of innovative mental health treatments and create the environment to take advantage of the future advancement in neuromodulation technologies, such as transcranial direct current stimulation (tDCS) (Woodham et al, 2024) and possibilities for extending TMS treatment into other mental health and physical health conditions eg OCD, PTSD and chronic pain management

TMS also promotes the community transformation agenda: the vision of the service is to build its working relationship with primary care in this area and, ultimately, for the TMS service to be delivered at primary care level, as in other health jurisdictions.

Who the service is for

People with DTD, which is a debilitating condition and for which there are very limited treatment options.

In the UK, TMS occupies an unique position in the treatment pathway, between the failure to respond to two antidepressant regimes and ECT. Without TMS there is a significant treatment gap between antidepressant medication and ECT. Its positioning means that it would be appropriate for service users:

- who have not responded to standard treatment approaches
- who have not tolerated standard treatment approaches or have actively declined it
- who do not want to elect ECT
- with significant physical health difficulties for whom receiving a general anaesthetic poses a significant health risk and so for whom ECT is not an option
- who have perinatal or post-partum needs and have declined standard treatment approaches for reasons associated with how they wish to care for their unborn/ baby (eg breastfeeding)

Level of need

1% of the Trust population experience DTD, some 27,000 people.

TMS is a treatment option for people experiencing DTD who have not responded to standard treatment approaches. 33% of service users in specialist care and 22% in primary care fail to respond adequately to two trials of antidepressants (Rizvi et al, 2014).

The service regularly has a waiting list of 3-6 months. It has not been promoted beyond a small number of mental health teams because of its capacity limitations.

Current Provision

TMS treatment is currently provided by the Physical Treatment Service. It provides TMS to 2 service users over a 4-week treatment period, 24 people with DTD each year.

Since commencing the TMS service there has been no dedicated budget for the TMS service, including the maintenance of the TMS machine or the associated medical equipment required to deliver the treatment. This is a risk to the continuation of the treatment and is formally recorded in the Risk Register.

Service proposal

The proposal is to provide an enhanced TMS service for an initial period of 24 months. If the impact of the enhanced TMS service is positive, a further funding application will be made at the end of the 24 months for the provision of a permanent service.

The model for the initial enhanced TMS service has been developed by a working group consisting of clinical staff and operational management across the Physical Treatment Service and the Trust Research and Innovation section.

The reasons for basing an enhanced service on two, rather than one machine, include:

- two machines would provide the capacity for treating the 4 categories of people that income generation and cost-savings rests on.
    - the 4 categories of people are: Russland service users; Russland staff; private patients; and out of area (OOA) service users
    - one machine gives capacity of 6-8 people every 4 weeks. If in a 4-week period, two of these were private patients, two staff members and one OOA, it would leave capacity for 1-3 Russland patients, which is similar to the current service
- two machines provide flexibility to respond to any variation in referrals of people from the four categories, eg more staff referrals

- two machines allow more people with DTD to be treated with the associated potential to minimise waiting times

An options analysis sets out the benefits and costs of each option:

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Option 2 (a rTMS service based on two machines) is the preferred option.

Initial enhancement of TMS

The TMS will be delivered by the Physical Treatment Service utilising two TMS machines.

The enhanced service will:

- operate a referral system based on the tested inclusion/ exclusion criteria of Redburgh Mental Health NHS Foundation Trust, which led the BRIGhTMIND Study
- initially, each month, provide treatment to 12 service users, alongside a maintenance service for 4 service users who, having previously benefitted from TMS, are referred by their GP because of their risk of relapsing. This promotes the integration agenda.
    - Maintenance treatment, for those referred by their GP, would be delivered in line with the current research: on one occasion over a 2-3 month period at the same prescription as their original one.
    - The capacity of the service to increase the number of service users receiving TMS safely and effectively will be kept under review.

Initial enhancement: service user's journey

At the initial consultation with a service user there will be:

- an assessment of the appropriateness of the treatment for the individual service user
- baseline measures of the impact of their depression on their functioning using the national minimum data set for the Mental Health Mission's Mood Disorder Workstream
- a consideration of the service user's capacity to consent to the treatment and
- a discussion and decision about whether to proceed. If proceeding, a decision on the protocol specific to that service user and the seeking of consent for the treatment.

The first treatment session requires 2 members of staff to deliver. Subsequent treatments require one member of staff, with one staff member on site to respond to any clinical issues. Immediately following the treatment, the service user can continue with their normal activities.

<u>Initial enhancement: service user treatment outcomes</u>

At the conclusion of the TMS treatment, the impact of the treatment on a service user's functioning will be reassessed using a minimum data set and recorded for the service's evaluation. The minimum data set would comprise: QID-SR, GAD-7, and WSAS. Alongside this, qualitative information on the impact of the treatment/service will be sought from service users through a specific feedback form. It is intended that the feedback form will be developed with the support of the Trust's Involvement Team/ a service user TMS group.

The final strand of evaluation is seeking qualitative information on the impact on staff involved in delivering the service.

<u>Initial enhancement: phased implementation</u>

The enhanced TMS service will adopt a phased implementation model to manage demand and mitigate against the development of a significant waiting list:

- 0-6 months: a period of 'bedding in', installing the new machines, recruiting and training new staff, clearing the current waiting list and first steps in developing the market for private provision
- 3-12 months: the service will be promoted to each of the community and inpatient teams to coincide with team 'away days.' This will also deliver awareness raising to clinicians to gain an understanding of the treatment and what it can offer their service users. As part of this process a working relationship will be developed with the Perinatal and Mother and Baby Unit Services. In a survey of Community Peri Psychiatrists in England, 32 of the 37 Peri Psychiatrists who responded indicated that they would want access to a TMS service for their service users. There is a case for prioritising referrals for treatment from inpatient services based on degree of illness and potential service utilisation reduction.
- 3 months onwards: promoting the private provision of TMS treatment in accordance with the market analysis
- from the commencement of the service, GPs would be able to refer direct, service users who had previously benefitted from TMS treatment and were considered at risk of relapse. This element of the model would promote they integration of primary and secondary care.

The current service user literature for the TMS service will be revised in co-production with the Trust's Service User Involvement Bank, the region's Health Literacy Team so that the information is accessible to a range of cultural and diversity needs.

It is anticipated an enhanced TMS service will deliver the following improvements in service user experience:

- increased choice of treatment options for people with DTD

- wider access to TMS treatment for people with DTD with proven clinical effectiveness
- a reduction in the waiting list for TMS treatment
- closer working arrangements with primary care services
- broadens the opportunity for shared decision-making with service users
- reduces health inequalities

Strategic drivers for the change and alignment with Trust priorities

This project is aligned with the:

NHS Long Term Plan Ambition (Adult Mental Health Services)
In the plan relating to severe mental illness, the support for adults and older adults with severe mental illness '…includes maintaining and developing new services for people who have the most complex needs…'.

Trust priorities
The proposed enhanced service model focuses on key priorities of the Trust to provide specialist mental health support to keep people healthy; and, to provide first class care: high-quality, evidence-based and safe services.

It also promotes the community transformation agenda: the vision of the service is to build its working relationship with primary care in this area and, ultimately, for the TMS service to be delivered at primary care level, as in other health jurisdictions. An initial step in this vision is referenced above (see heading: Initial enhancement: staged implementation).

<u>Strategic drivers</u>

	In addition to meeting the Trust's priorities and building on its 'special position', there are important strategic drivers that are embodied in this proposal: • Provision of clinically excellent care using a clinically effective, and safe treatment with lasting effects for service users experiencing difficult to treat depression • Responds to service user wishes and maximises treatment choice • The number of service users benefitting from TMS treatment is increased and the Trust's offer for excellent and quality care is enhanced. • Enhances staff recruitment and retention by enhancing the knowledge, skills and expertise of clinicians delivering VNS and supports a learning and career development culture • To be at the vanguard of delivering the NHS' next generation of innovative mental health treatments and create the environment to take advantage of the future advancement in neuromodulation technologies, such as transcranial direct current stimulation (tDCS) (Woodham et al, 2024). The business change advocated in this proposal was not set out in the Annual Plan for the business area.
3. Impact assessment of the change	Please provide details of your assumptions and the impact this proposed change will have, covering the assumptions and impact on: • Delivery of quality standards • Changes in activity • Your workforce – include amended workforce plan if necessary • Your contracts with commissioners • Wider impact on the community • Contribution to the health and social care system • Your wider colleagues across the Trust Group. Where the change involves NTW Solutions' services and/or properties, please detail

the changes that may be required to the Trust's contracts with NTW Solutions and/or contracts that NTW Solutions manages for the Trust (including leases; and

- Your suppliers.

Delivery of Quality Standards

For each service user, the impact of the service will be measured using the clinical outcome measures: QIDS-C, GAD-7 and WSAS.

On an annual basis the service will be reviewed and the analysed outcome measures taken to the Physical Treatment Service Standards Group. Any other service audits will also be taken to this group.

Changes in activity

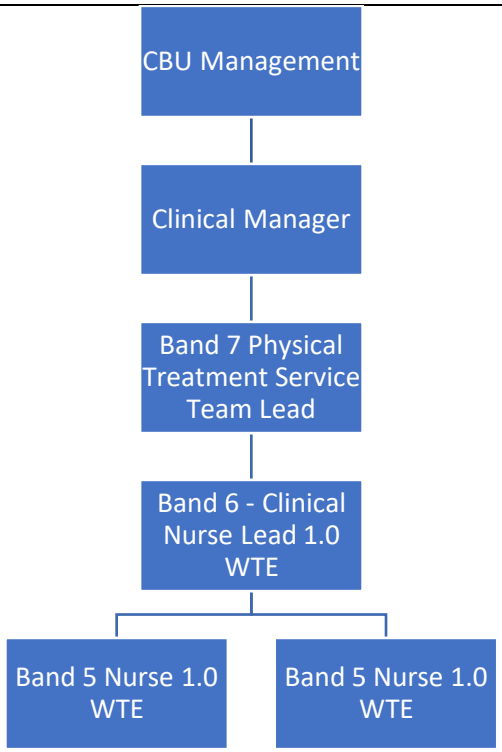
The service proposal will enable more service users with DTD to access TMS treatment. The numbers accessing this treatment option will increase from 2 servicers users each month (24 each year) to between 12-16 every 4 weeks (156-208 each year).

Although mainly utilised as a treatment for those service users with difficult to treat depression, it is envisaged that in the future this treatment option will become more mainstream and sit as an option alongside standard primary care pharmacological treatment offers.

It is important to note that ECT will continue to be a required treatment option for some service users.

Workforce

The TMS service will sit and be delivered within the Physical Treatment Service and its operational team and operational governance.



Clinical and management leadership would be provided by the Physical Treatment Service. The additional staff would be 2 x Band 5 nursing staff in line with the Royal College of Psychiatrists' guidelines, which are currently in draft. The new staff would be trained by the current Band 6. The training model would be a competency one and will take between 4-8 weeks to complete, depending on the number of service users receiving the treatment in that period.

Contracts with Commissioners

Currently there is no contracted commissioning for the provision of a TMS service. The business case is to be considered by the Care Group Directors and the Executive Management Group.

Wider impact on the community

An enhanced TMS service will have a positive impact on the community. Some of these impacts are:

- an increase in service users' choice of treatment options, more tailored to their difficult to treat depression
- an increase in access to an efficacious treatment option for service users experiencing difficult to treat depression
- a mitigation of the need for GPs to approach the Integrated Care Board for private funding for TMS treatment
- a reduction in the current waiting times for TMS treatment of 3-6 months
- an improvement in equity of health care treatment between people who can afford to pay for private TMS treatment and those who cannot

Contribution to the health and social care system

The enhanced TMS service would increase the accessibility of this treatment option to service users from secondary and tertiary care.

Preliminary Trust data suggests that the service would reduce in-patient admissions and use of crisis referrals.

It is envisaged that any future service expansion would enable primary care access via GP referral, without the need for secondary care involvement. Primary care would be able to refer service users experiencing DTD to the TMS service, improving the integration of mental health services across primary and secondary care.

An enhanced TMS service, delivered by the Physical Treatment Service would be able to continue to develop the evidence base for this approach and enable the Trust to be at the forefront of the development of the TMS national treatment protocol and the national innovation of TMS, both developments informing local service provision. These developments will be supported through our specialist clinic services and

	our links with the local University and the Trust Research & Innovation Department. **Wider colleagues across the Trust Group** The proposed change is not expected to impact wider colleagues across the Trust Group. **Suppliers** There is a working relationship with the suppliers of the TMS medical equipment. A formal contractual relationship was not considered necessary by the suppliers.
4. Service user and carer engagement	Describe how service users and their carers have been (or will be) involved in this project and how they will benefit once it is implemented **Service user involvement in this project** Service user involvement and participation in the service proposal is important to the clinical team. We have approached different service user involvement forums to gather views about TMS. The Service User Involvement Bank have reported that one of their contributors responded to them say: *"I would love to try this, is it now available on the NHS in this region as it hasn't been until now if it is?"* We have communicated with the Trust service user representative in the BRIGhTMIND Study to find out their views on the service proposal. They have experienced DTD difficult to treat depression for almost three decades. • While they themselves did not receive the active TMS treatment in the Study, they were linked up with another representative who did receive the active treatment and reported that it had '*transformed their life'* after 2-3 months.

- They said they would like to have the option of TMS, which they see as a 'personalised treatment approach' for difficult to treat depression. They have been treated with ECT, which was effective, but they found it caused the loss of autobiographical memory that has not been recovered. They believe that the current service proposal should include inclusion and exclusion criteria because of the cost of the treatment. They think it is '*a fantastic thing*' to enhance the TMS service and have offered to be involved in a service user group to support the service development.

When we met with six service users from a formal research involvement group linked to the Trust:

- each of them have experiences of DTD difficult to treat depression, none of them had heard about TMS
- each of them wanted to have access to the treatment. In the first two Case Studies below, two of them set out their individual stories and their views about having access to TMS

A presentation on TMS to the Redburgh Involvement Partnership Meeting on 18th October 2024 resulted in a positive response to the adoption of TMS in the treatment of depression and several health care groups expressed an interest in promoting TMS with its users.

In 2023, a national survey of 54 mental health trusts in which 21 responded, 13 reported that their service users had asked about their Trusts offering neuromodulation therapies (the majority of Trusts offering neuromodulation were offering TMS). Three Trusts reported they had formally commissioned an ability to offer TMS (Hall and Baxter, 2023).

<u>Service user case studies and feedback on TMS</u>

	The fourth and fifth documents embedded here are the personal stories of a carer and servicer user who have benefitted from TMS treatment. [5 x case studies embedded but not shared in this example] <u>Service user participation in the project team</u> Working with the Service User Involvement Team, we would like to facilitate a service user group to support the development of the TMS service. We cannot anticipate what development areas they would be willing to support us but there are a range of possibilities including: • the development of a feedback form for service users receiving treatment • the development of the information leaflet for TMS • supporting service users new to the TMS treatment • contributing to writing future service proposals • communicating about the TMS service with primary and secondary care services • the review of the service Research demonstrates that service user involvement in co-design and co-production of mental health services are associated with more positive and substantial outputs relating to service effectiveness than more limited involvement methods (Ezaydi et al, 2023).
5. Describe how this project will contribute to the relevant community and the wider health and social care system	Note - The Trust wants to contribute to the health and wellbeing of the wider population and to contribute fully to the creation of an integrated health and social care system. **Contribution to the health and well-being of the wider population** Depression is the third commonest cause of disability. 1% of the Trust population experience DTD, some 27,000 people. Of this 27,000, 2 people each month are currently provided with TMS treatment,

	which will increase to up to 16 people every 4 weeks (208 per annum) under the service proposal. Service users with DTD are more likely to have severe depression and higher rates of hospitalisation (Costa et al 2022). Prolonged periods of inadequate treatment for depression contribute to a higher risk of chronicity, comorbidity and suicidality, emphasising the need for effective treatment options for service users with difficult to treat depression (Eaton et al, 2008). It is estimated that the impact of mental ill health costs the UK economy £118 billion per year. In 2020/1, the estimated cost of poor mental health to UK employers was £56 billion.
6. Funding and finance	Provide a narrative explanation here of the financial impact of this business change proposal, including details of revenue income and/or capital investment required to fund this business change and where it will come from. If applicable, confirm that commissioners support the proposed change. Address any issues that were raised by approvers on the Outline Business Case in respect of finance. Indicate the additional funds required to deliver this project, in the table below. Embed/attach full costings to include VAT, depreciation etc. Use **costing template.** Proposed service costs The cost to the Trust of establishing the enhanced TMS service based on two Magstim (with Stim Guide) machines would be £383,030, comprising: • the investment costs of 2 x TMS machines (including a 2-year Preventative Measures Package for each machine): £184,400. • the costs of the service for 2 years, namely 2 x Band 5 staffing costs and consumable costs: £198, 630:

<table>
<tr><td></td><td colspan="5">The upfront capital costs and costs of the service would be borne by Russland Trust on the basis that the service would repay this cost by: supporting the treatment of absent staff; generating income through providing the service to other locality trusts and through providing the treatment privately to self-funders; and, supporting the reduction in mental health service utilisation

[The full costings are embedded in a separate spreadsheet]</td></tr>
<tr><td></td><td>Agreed baseline from annual plan</td><td>Additional capital expenditure £</td><td>Additional revenue expenditure £</td><td>Source of funds</td><td>Financial benefits £</td></tr>
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<tr><td>Y4 27/28</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Total</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>7. Green Plan: Explain how the proposed business change will contribute to the delivery of the Trust's Green Plan</td><td colspan="5">Those who are engaging in business change projects must demonstrate how the proposed change will deliver social, environmental and/or carbon reduction benefits. They must be familiar with the aims and objectives of the Green Plan and align all business change one or more of the seven Aims set out in the Green Plan. [include link]

Address any questions or queries that were raised by EMG / Board on the outline version of this Business Case, providing further clarity and detail where this was requested</td></tr>
</table>

The proposed business change aligns with TRUST Climate Health Ambition 5: '*Ensuring we consider the social and environmental impact of any decisions we make.'*

The position of the TMS service in the treatment pathway means that it is an appropriate treatment before the option of ECT. If it is engaged in this way, it can in some instances reduced/ avoid a need for ECT. There are social, environmental and carbon footprint benefits that flow from this happening:

- The staff team to deliver TMS is smaller than that required for ECT. The team to administer ECT includes a consultant psychiatrist and consultant anaesthetist, anaesthetist assistant and three trained nurses
- TMS does not require the involvement of a consultant anaesthetist or anaesthesia
- The TMS treatment option involves a shorter period of hospital attendance by the service user than ECT. For ECT, treatment is delivered twice a week, typically for 12 sessions (6 weeks); TMS can be delivered within one week
- TMS treatment does not require service users to remain in hospital following the treatment. Service users who have received ECT and do not have a carer to support them overnight require in-patient admission
- TMS treatment utilises less medical equipment and no medications. To deliver ECT it requires gel for ECT, cannulas, syringes, medications, stickers for ECG and EEG.

If the clinical outcomes of the service users who have received TMS treatment in the Trust were replicated in an enhanced service, then its positive effect, including moving people into remission, would have a significant impact in terms of reducing the utilisation of secondary and tertiary care services.

8. Provide details of other options considered and discounted, and why the preferred option was selected	This is the options analysis, this must contain at least "do nothing" and the preferred option. Where approvers of an outline version of this Business Case asked for further options to be considered provide details/the outcome **Options analysis** <u>(1) Do nothing/ No change</u> The one TMS machine in operation would be utilised until the end of its life span with staff with the running costs being absorbed by the ECT budget. The clinically effective DTD treatment option for service users would be lost, along with clinicians' knowledge and skills; the Trust's national reputation as a leader in TMS; future TMS treatments for serious mental and physical health problems; and, the opportunity to reduce financial pressures on the Trust. <u>(2) Immediate cessation of all TMS provision for difficult to treat depression</u> Risks - as for (1) above and service users receiving or referred to receive TMS treatment would cease treatment without any notice, which may lead to formal complaints being made against the Trust. <u>(3) Maximisation of the life of the TMS service with a planned cessation</u> Care plans for TMS treatment would be fulfilled for service users receiving or referred to receive treatment. Risks – as for (1) above. <u>(4) Development of an enhanced TMS service for a pilot period of 24 months and then review</u> The current TMS service would be expanded for a specific period. Its expansion would: increase accessibility of this treatment option to service

<table>
<tr><td></td><td colspan="5">users of secondary and tertiary care services; enhance service user choice; reduce financial pressures on the Trust; develop clinicians' knowledge and skills; enable future TMS treatment options for mental and physical health problems; and, consolidate the Trust's national reputation in TMS treatment;

Details of the benefits and drawbacks of each option are contained in the document below:

 
Options%20Benefits%20and%20Risks%2(</td></tr>
<tr><td rowspan="3">9. Timescale</td><td>Process start</td><td>Full business case (FBC) approved</td><td>Development</td><td>Go live</td><td>Benefits delivered</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Date of submission</td><td></td><td>6 months post-FBC approval</td><td>6 months post-FBS approval</td><td>12 months post-FBC approval</td></tr>
<tr><td>10. Detail the critical dependencies on which project delivery will rely</td><td colspan="5">Describe the third parties, consents, approvals etc. that your project will be dependent upon for delivery, with timescales.

For 10.i – 10.iv below, give details of requirements, discussions and agreements from subject experts.

In signing, or providing approval via email, I agree to the information contained in this business case in so far as it relates to my department or business unit.</td></tr>
</table>

10.i Digital services	In signing, or providing approval via email, I agree to the information contained in this business case in so far as it relates to my department or business unit
	Name – Date –
10.ii Information governance	Data Protection Impact Assessment (DPIA) included? I agree to the information contained in this business case in so far as it relates to my department or business unit.
	Name – Date –
10.iii Estate solutions	I agree to the information contained in this business case in so far as it relates to my department or business unit.
	Name – Date –
10.iv Pharmacy	I agree to the information contained in this business case in so far as it relates to my department or business unit.
	Name – Date –
10.v Equality impact assessment	As part of the investment procedure/ process, it is vital that each business case presented to Executive Management Group (EMG), and subsequently approved by Board of Directors, includes a thorough Equality Impact Assessment. This is to ensure that every effort is made to

	minimise any barriers the investment(s) may present to those of each protected characteristic.
	Name – Date –
11. Explain how you intend to manage, deliver and implement this change project	You need to describe the project management approach and also how the change itself is to be achieved and implemented Include here details of the delivery mechanism, e.g. through existing resources, establishing appropriate project management/governance, bringing in Group expertise, a procurement of external providers or other – include details of dependencies on other areas of the Group, including Commissioning & Quality Assurance, IT, Estate Solutions, IG and others. Attach or include a Project plan if this is available The project management approach to be employed is the six-stage project management approach (NHS England and NHS Improvement), which is a framework for managing improvement projects in the NHS. Stages 4, 5 and 6 are the key stages requiring implementation to achieve the change of this service proposal. The Project Plan (embedded here) sets out how the change itself is to be achieved and implemented. The delivery mechanism for the enhanced TMS service is through existing resources augmented by a service user group. Project governance will be delivered through the clinical and management leadership team of the Physical Treatment Service.

	Gantt%20Chart%20v1.docx
12. Risks and issues	Explain any risks and/or issues that may arise in the delivery of this project or any that could occur if the business change project is not approved. Explain this by reference to the Trust's Risk Management Strategy and Risk Policy and detail any risks or issues that have been or are to be formally recorded in Risk Registers. **If the business change project is not approved** The risks and/or issues that may arise if the business change project is not approved are set out in the document below: Business%20change%20not%20approved **If the business change is approved** Business%20change%20approved%20-%;
13. Recommendation	Confirm the preferred option and recommend it for approval by EMG (Trust Board if at that level) Option 4 is recommended for approval by the Executive Management Board.

14. Further approvals	Detail any further approvals that would be needed in order to implement the proposal, ie NHSI, Commissioners, others, and if any, timescales for these Not applicable.

Sponsor Sign Off

As Project Sponsor I approve the contents of this business case for submission to EMG.

Sponsor ..... Date .....

Guidance note - where one of the sections of the business case template is not relevant to a project, the Project Sponsor or Author may state "not applicable". However, if the decision makers deem this area to be relevant this will be raised at EMG or Board.

Reference List

BRIGhTMIND (2024), Nature Medicine, Vol. 30, Feb 2024, ps 403-41: https://doi.org/10.1038/s41591-023-02764-z

Costa, T., Menzat, B., Engelthaler, T., Fell, B., Franarin, T., Roque, G., Wei, Y., Zhang, X., and McAllister-Williams, R. (2022). The burden associated with, and management of, difficult-to-treat depression in patients under specialist psychiatric care in the United Kingdom. J Psychopharmacol 4 May 2022: doi: 10.1177/02698811221090628

Dalhuisen, I., Smit, F., Spijker, J., Oostrom, I., Exel, E., Mierlo, H., de Waardt, D., Arns, M., Tendolkar, I. and Eijndhoven, P. (2024). TMS combined with CBT as a next step in antidepressant non-responders: a study protocol for a randomized comparison with current antidepressant treatment approaches. Am J Psychiatry 7 Aug 2024:appiajp20230556. doi: 10.1176/appi.ajp.20230556

Eaaton, W., Shao, H., Nestadt, G., Hochang, L., Bienvenu, O., and Zandi, P. (2008). Population-based study of first onset and chronicity in major depressive disorder. Arch Gen Psychiatry 2008 May;65(5):513-20. DOI: 10.1001/archpsyc.65.5.513

Ezaydi, N., Sheldon, E., Kenny, A., Taylor Buck, E., and Weich, S. (2023) Service user involvement in mental health service commissioning, development and delivery: A systematic review of service level outcomes. Health Expect Jun. 26 (4), ps 1453-1466. doi: 10.1111/hex.13788

Hall, R. and Baxter, E., (2023) 'Understanding the current position on Treatment Resistant Depression in England', Midlands Clinical Senates - Proactive Projects (midlandssenates.nhs.uk

Newcastle Health Innovation Partners, (2025) North East/ North Cumbria Suicide and Self-harm Preventive Research Collaborative. A presentation to the Integrated Care System Evidence and Evaluation Meeting, 17th January 2025.

NICE (16th December 2015). Repetitive Transcranial Magnetic Stimulation for Depression. https://www.nice.org.uk/guidance/IPG542

Slotema, C., Hoek, J. and Sommer, I (2010) Should we expand the toolbox of psychiatric treatment methods to include Repetitive Transcranial Magnetic Stimulation (TMS)? A meta-analysis of the efficacy of TMS in psychiatric disorders.
J Clin Psychiatry 2010 Jul;71(7):873-84.
doi: 10.4088/JCP.08m04872gre. Epub 2010 Mar 9. PubMed (nih.gov)

Sharbafshaaer, M., Gigi, I., Lavorgna, L., Esposito, S., Bonavita, S.,Tedeschi, G., Esposito, F. and Trojsi, F. (2023). Repetitive Transcranial Magnetic Stimulation (TMS) in Mild Cognitive Impairment: Effects on Cognitive Functions—A Systematic Review. J Clin Med. 12(19): 6190.

Royal College of Psychiatrists (2017) Statement on Repetitive Transcranial Magnetic Stimulation for Depression. ectcommittee-repetative-transcranial-magnetic-stimulation-statement-may18.pdf (rcpsych.ac.uk)

Rethink, (2024). 'Right Treatment, Right Time. How delays in accessing care and treatment are pushing people into crisis'. right-treatment-right-time-report.pdf (rethink.org)

NHS England and NHS Improvement, (undated). Project management : an overview. Online Library of Quality Service Improvements and Redesign Tools: Layout 1 (dchft.nhs.uk)

Woodham, R.D., Selvaraj, S., Lajmi, N. et al. Home-based transcranial direct current stimulation treatment for major depressive disorder: a fully remote phase 2 randomized sham-controlled trial. Nat Med (2024). https://doi.org/10.1038/s41591-024-03305-y