2025-2026 FOUNDATION PLAN IMPLEMENTATION
PROJECT EXCEPTION REPORT

Exec Sponsor:	N/A	**Aim of Project**: Welsh residents have equitable access to effective treatments (ATMPs) including cellular therapies and gene therapies to maximise survival and quality of life. (SP1 SS3)	**Project Start:**	**Oct-25**
Senior Responsible Officer:	Iolo Doull		**Project End:**	**IMTP**
Project Manager:	N/A		**Reporting period:**	**Q3**

Overall Status:

1. Overall Status Summary	2. Achievements - What went well this period	3. Set backs - What didn't go so well this period
Significant Slippage WGov supported the costs of both the medicines and the infrastructure costs for the delivery of cellular CAR-T therapies for patients in Wales, as yet there is no such process for gene therapies. There is ongoing engagement but no sustainable pathway established for gene therapies, specifically exagamglogene autotemcel, which is limited by funding in Wales.	NWJCC commissioning policies have been developed following NICE approval.	Delayed patient access to NICE recommended, NWJCC commissioned treatment (exagamglogene autotemcel) due to limited funding in Wales for new pathways and additional resource. Unable to secure funding at this stage to establish new gene therapies pathways or support pre/post treatment visits in Wales, limiting access for patients.

4. Upcoming Key Milestones or Deliverables	Original stated milestone	Expected Delivery Date	Confidence Rating	The Path to Green - How you will get back on track / keep on track	5. What's ahead for the workstream over the next reporting period
Develop commissioning policies	31/03/2026 (Q4)	31/03/2026 (Q4)		Commissioning policies being developed following NICE approval but publication is delayed pending approval of site delegation in specific ATMPs - exagamglogene autotemcel and etranacogene dezaparvovec.	Confirm desiginated provder sites and publish policies.
Work with stakeholders to commission pathways and designate providers	IMTP	IMTP		Pathways identified but funding needs confirmation, discussions ongoing with WGov. WGov currently fund the medicines cost but not the service costs wexagamglogene autotemcel and etranacogene dezaparvovec pathways. NWJCC supporting etranacogene dezaparvovec delivery costs until April 2026 to ensure service set up within Cardiff and Vale UHB and delivery of treatmement to the first patient. Recurrent funding to support continuation of the service will be included in the IMTP, with wider strategic discussion on how gene therapies should be funded and delivered in Wales. Active engagement with WGov to ensure Welsh patients have the same equity of access to gene therapies as the rest of the UK.	Request made to WGov to explore pathway funding opportunities. MoU in place with Advanced Therapies Wales and ongoing national collaboration to explore complex pathways through the Coallition of the Willing group (Chaired by Suzanne Rankin).
					Inclusion of funding for ATMP delivery in IMTP if alternative funding not secured.

6. Risk Management - Summary of Highest Rated Risks

Summary of Risk	*Likelihood*	*Impact*	*RAG*	*Mitigating Actions*
Lack of funding for gene therapy pathways. If..we don't have the resourcing to support gene therapy delivery in Wales Then…we will be unable to develop services and deliver gene therapies in Wales Resulting in… those eligible for gene therapy either not receiving treatment or travelling long unnecessary distances, leading to poorer outcomes, inequity and inequality	4	4	16	• Identify potential funding opportunities, request to WGov made to consider gene therapy service funding and specifically funding for pathways for etranacogene dezaparvovec and exagamglogene autotemcel or inclusion in IMTP • Early horizon scanning for complex therapies to ensure early opportunity to plan pathways • Initiate early planning and preparation discussions to identify possible delivery centres and optimal pathways • Monitor impact on delivery • Develop relationships with NHS England to ensure consistent pathways and learnings
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7. Issue Management - Summary of the Highest Rated Issues

Issue Description	*Priority*	*Mitigating actions*	*Escalation*