## To:

The Innovation Passport Team
Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

**Subject:** Cover letter of Innovation Passport Application – Vitamin D Transport Protein (VDTP) for Autism Spectrum Disorder

Dear Innovation Passport Team,

On behalf of Vita Vitalia Ltd, I am pleased to submit our application for an **Innovation Passport designation** under the Innovative Licensing and Access Pathway (ILAP) for our investigational biologic, **Vitamin D Transport Protein (VDTP)**.

VDTP represents a biologically native, immune-modulating therapy aimed at addressing the serious unmet clinical need associated with immune dysfunction in individuals with Autism Spectrum Disorder (ASD). Our submission includes the completed Innovation Passport Application Form and supporting documents, including a separate Plain English Summary, as required by the guidelines.

The team at Vita Vitalia is committed to collaborating with the MHRA and ILAP partners to advance the structured clinical development of VDTP in line with regulatory guidance and patient needs. We are excited to engage in early dialogue regarding the Target Development Profile (TDP) and explore opportunities to accelerate the development of this vital therapy.

Should you require any further information or clarification, please do not hesitate to contact me directly.

Thank you for considering our application. We look forward to the opportunity to work collaboratively with the MHRA, NICE, and other ILAP partners.

Yours faithfully,

## **Garry Bower**

Director Vita Vitalia Ltd