



Medicines & Healthcare products
Regulatory Agency



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Dr Rinat Ezra
IMPERIAL COLLEGE LONDON
JOINT RESEARCH COMPLIANCE OFFICE,
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UNITED KINGDOM

12/02/2024

Dear Dr Rinat Ezra

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference:	CTA 19174/0439/001-0003
IRAS ID:	1005848
Product:	Sargramostim (Leukine)
Protocol number:	A4-1- 22SM8039
Substantial Amendment Code Number:	AM001

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to inform you that the Licensing Authority, having reviewed your application in collaboration with the Research Ethics Committee (where applicable), accepts the proposed amendment to your clinical trial authorisation (CTA), received on 24/01/2024.

PHARMACEUTICAL

This amendment may therefore be made.

If applicable, you should ensure your trial details have been updated on the database where you have registered your trial.

You are reminded that where it is appropriate, the Ethics Committee should also be notified of amendments.

You are reminded that from 1 January 2022 you will need to comply with the requirements specified in the following guidance, where applicable:

Import of IMPs from listed countries to GB:

<https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries>

Supply of IMPs to Northern Ireland:

<https://www.gov.uk/guidance/supplying-investigational-medicinal-products-to-northern-ireland>

Substantial amendments to clinical trials:

<https://www.gov.uk/guidance/guidance-on-substantial-amendments-to-a-clinical-trial>



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Any required substantial amendment to your Clinical Trial Authorisation should be submitted and approved as soon as possible and before 1 January 2022.

Yours sincerely,

**Clinical Trials Unit
MHRA**