

21 February 2022

Funding and costs of Kalydeco (Ivacaftor) Trial: NCT00909532 (Cystic Fibrosis) – Update following response of 29 September 2021

Note that this request pertains specifically to “Belfast City Hospital”.

Under the Freedom of Information Act 2000, please provide me with all of the following:

1) Details of all parties that have contributed funding to the Trust in relation to the Kalydeco (Ivacaftor) trial NCT00909532 being conducted at your site/s.

Vertex Pharmaceuticals

2) A list of all sites within your Trust that Kalydeco (Ivacaftor) trials have been conducted at.

Royal Belfast Hospital for Sick Children (RBHSC) and Belfast City Hospital sites opened this trial (NCT00909532)

3) Numbers of Kalydeco (Ivacaftor) trial participants at each trial location, for the NCT00909532 trial.

RBHSC	0
BCH	7

4) Number of staff involved in conducting the trial at each trial location, listing their roles, for the trial, NCT00909532

RBHSC	6 staff	} Made up of both research nurses and medical staff
BCH	8 staff	

5) What costs were incurred by the Trust in order to conduct the Kalydeco (Ivacaftor) trial, NCT00909532? If a document does not state the total budget or cost of a trial, but lists the actual or expected costs of any aspect of the trial, it would also be subject to this request. If a document states the yearly budget for a clinical trial, that would be pertinent as well. This includes per-patient costs in conducting the trial. The simplest response would be to provide the cost in GBP of either the budget for the trials or the actual outlays, and both if that is possible.

Total procedure costs (per participant) - £11,662
Total Extra Costs (including participant travel) - £4662

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6) A breakdown of any funding received from internal and external sources in order to conduct the Kalydeco (Ivacaftor) trial, NCT00909532. Please break funding down into i) funding from public (governmental) bodies, ii) private entities, and iii) philanthropies/charitable bodies. Please include the full name of the funding body. Please specify amounts in GBP. (Please provide this as an excel spreadsheet)

Vertex Pharmaceuticals Incorporated - £27,067

7) A record of all expenses incurred in conducting the Kalydeco (Ivacaftor) trial, NCT00909532.

	INCOME	£
Invoices raised		(27,067.25)
	SPEND	
Patient travel		675.20
Pharmacy Fees		250.00
R&D Fees		500.00
Miscellaneous (Unable to provide back up as details now archived)		2,707.74
Trust Overheads		7,808.02
		11,940.96
Balance		(15,126.29)