Australian Government
Department of Health
Therapeutic Goods Administration

Regulatory Affairs
Quintiles Pty Ltd
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Chatswood NSW 2067

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CTN SCHEME: ACKNOWLEDGEMENT OF CLINICAL TRIAL NOTIFICATION

Your notification to conduct a clinical trial under the Clinical Trial Notification (CTN) Scheme, pursuant to Schedule 5A of the *Therapeutics Goods Regulations 1990* and/or Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* has been received by the Therapeutic Goods Administration (TGA).

Study Sponsor: Quintiles Pty Ltd (20399)
Protocol Number: CBT124/NHV/001
Application ID: CT-2016-CTN-01780-1 v1

Details of Therapeutic Goods Notified:

- **Medicine(s):**

Trade / Product / Code Name	Ingredient Name(s) Quantity Unit	Dosage Form	Type of Container
EU-sourced Avastin (bevacizumab)	Bevacizumab – 25mg/mL	Injection, solution	Vials
US-sourced Avastin (bevacizumab)	Bevacizumab – 25mg/mL	Injection, solution	Vials
CBT124 (Cipla BioTec bevacizumab)	Bevacizumab (CBT-124) – 25mg/mL	Injection, solution	Vials

Details of Site(s) Notified:

Site Name	State	Site Expected Start Date
CMAX-– a division of IDT Australia Limited	SA	06/07/2016

In notifying this clinical trial the sponsor of the trial has acknowledged that:

- the sponsor is taking overall responsibility for the trial
- the relevant goods only remain exempt by reason of their use in the clinical trial only for so long as:
    - the approval of the goods for the trial has been given by the sponsor, (if the sponsor is conducting the trial), or by the body or organisation conducting the trial for the sponsor, having regard to the advice of the ethics committee responsible for monitoring the conduct of the trial, on terms no less restrictive than terms advised by that committee
    - the sponsor has not received advice from the ethics committee that is inconsistent with the continuation of the trial
    - the requirements in regulation 12AD of the Therapeutic Goods Regulations 1990 (in the case of therapeutic goods other than medical devices) and regulation 7.5 of the Therapeutic Goods (Medical Devices) Regulations 2002 (in the case of medical devices) are complied with, including that the use of therapeutic goods in the trial must be in accordance with the Guidelines for Good Clinical Practice and the National Statement on the Ethical Conduct in Research Involving Humans published by the National Health and Medical Research Council, as defined in the Therapeutic Goods Regulations
    - the Secretary has not under Item 3 of Schedule 5A of the Therapeutic Goods Regulations (in the case of therapeutic goods other than medical devices) or Item 2.3 in Part 2 of Schedule 4 of the Therapeutic Goods (Medical Device) Regulations 2002 directed that the trial not be conducted on the basis that the Secretary has become aware that to conduct the trial would be contrary to the public interest
- the Secretary can under the *Therapeutic Goods Act 1989* (the Act), require the sponsor to provide specified information or documents relating to any exempt goods
- the Secretary can provide information obtained in response to an authority or the Commonwealth, or a State or Territory that has functions in relation to therapeutic goods or the registration or medical practitioners or pharmacists in the relevant State or Territory
- it is an offence under the Act to fail to provide that information or documents required by the Secretary, or to provide information or documents that are false or misleading in a material particular, to the Secretary
- it is a requirement of the Guidelines on Good Clinical Practice that the sponsor report all serious and unexpected adverse reactions arising from the use of the relevant goods in the trial to the TGA
- it is a serious offence under Commonwealth law to provide information for the purposes of this notification that is false or misleading in a material particular.

Please note that:

i. the Therapeutic Goods Administration has not carried out an assessment of the quality, safety or efficacy of any therapeutic good in relation to this notification.

ii. in the event that the Secretary of the Commonwealth Department of Health becomes aware that to undertake or continue the clinical trial would be contrary to the public interest, the Secretary has the authority to direct that use of the therapeutic good(s) for this clinical trial must cease.

If there are any changes to the trial details notified to the TGA, it would be necessary for the sponsor to update the relevant fields on the online CTN form.

Kind Regards

Emmeline Maybanks
Clinical Trials Administration
Experimental Products Section

07 July 2016