World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Desk Assessment of Contract Research Organization (CRO)

Part 1	**General information**	
Company information		
Name of Company	Altasciences	
Corporate address of Company	575 Armand-Frappier Blvd Laval (Quebec) Canada, H7V 4B3	
Inspected site		
Name & address of CRO	Clinical site: 1200 Beaumont Avenue Mount-Royal Quebec, H3P 3P1 Canada	
Desk assessment details		
Date of review	Start date: 20 Dec 2018 End date: 21 Dec 2018	
Product and study information covered by this desk assessment	Study start date: 29 Oct 2011 A randomized, 2-way crossover, single dose study to assess the bioequivalence of a new formulation of a medicinal product in healthy volunteers under fasting conditions.	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last)**	
MHRA - UK	Dates of inspections:	6-10 Nov 2017
	Type of inspections:	Routine
	Unit:	Bioanalytical and clinical activities of four BE-studies
	Type of study covered:	BE-study
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	Not applicable since the site has not previously been inspected by WHO.	
Part 4	**Introduction**	
Brief description of the site's activities	Altasciences provides integrated package of outsourced services, including clinical conduct of phase I through Phase II, proof-of-concept studies, bioequivalence studies, as well as Good Laboratory Practices (GLP) and non-GLP bioanalytical testing services along the drug development	

	continuum. The Canadian Altasciences site employs approximately 600 employees. The company was established as CRO in 1992 providing multiple research services for pharmaceutical, biotechnology and generic drug industries. The clinical site is equipped with 265 beds housed within 5 clinical units. Three of these units are dedicated Phase 1 clinics, incorporating 75 hospital beds capable of intensive monitoring.

Abbreviations	**Meaning**
CCs	Calibration Curve standards
CAPA	Corrective and preventive action
CROMF	CRO master file
GCP	Good clinical practices
GLP	Good laboratory practices
NC	Non-conformity
NRA	National regulatory agency
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
SOP	Standard operating procedure
SRA	Stringent regulatory authority

Part 4	**Summary of the assessment of supporting documentation**

a) Clinical trial license granted by the local authority:
Prior to the initiation of a clinical trial in Canada, sponsors must file a Clinical Trial Application (CTA) with Health Canada. Health Canada reviews the Clinical Trial Application (CTA) and notifies the sponsor within 30 calendar days if the application is found to be deficient. If the application is deemed acceptable, a No Objection Letter (NOL) is issued within the 30-day review period. Changes to a previously authorized CTA must be submitted to Health Canada either as a CTA Amendment or a Notification. In the case of Altasiences, a NOL issued for the conduct of the study, along with the Notification of change was submitted, dated 14 Sep 2011 and 19 Oct 2011 respectively.

b) CRO Master File:
The CRO master file, version 1.0, approved on 28 Sep 2018 was provided. The Master File was arranged in accordance with the WHO guidelines for the preparation of a contract research organization master file, Annex 7, no 957, 2010.

c) List of all regulatory inspections performed in the last 3 years and their outcomes:
The list of regulatory inspections was available in the CROMF, providing the last ten year's history. All inspections on the list were declared closed. The most recent stringent regulatory inspection performed was conducted by MHRA on November 2017.

The company was also inspected by US FDA in December 2017 which was more relevant to the study in the scope of the Desk Review. However, the Establishment Inspection Report (EIR) for this inspection wasn't yet made available by US FDA. The number of the observations made was recorded as None in the list of GCP and GLP Regulatory inspections at Altasciences

d) Local NRA inspection report:

The company was inspected by SCC for Health Canada in April 2018 and March 2017 in the last three years. The reports, consisting of a list of observations were reviewed. One of the reports also included the relevant CAPAs provided by the CRO. The authority only conducts inspections for pre-clinical work.

e) Copy of any warning letter, or equivalent regulatory action, issued by any authority for the site:

Altasciences have not received a warning letter or any equivalent regulatory action at the time of this desk review.

f) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the studies conducted for WHO product(s) has been performed and all matters dealt with:

The QA statement for the study was signed on 14 Mar 2012, confirming that the personnel mentioned in the QA statement performed the audit of this project, at different stages during the project according to the ICH GCP Guideline (April 1996), which included the ethical requirements of the Directive 2001/20/EC (4 April 2001), at the dates listed. It was also stated that the content of the report reflected the raw data.

g) IRB/IEC clinical trial approval (including the approved protocol, the amended protocol and consent form):

The project approval letter issued by ETHIPRO, an Independent Research Ethics Committee was signed on 25 Feb 2011.

The amended protocol version 3 Oct 2011 and related documentation were approved by ETHIPRO on 3 Oct 2011.

h) Additional documents submitted:

None.

Part 5	**Conclusion**

Based on the GCP/GLP/BE evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Altascience*** located at ***1200 Beaumont Avenue, Mount-Royal, Quebec, H3P 3P1; Canada*** is considered to have performed the studies submitted to WHO PQT under an acceptable level of compliance with WHO guidelines.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 6	List of WHO guidelines referenced in this inspection report

1. Guidance for organizations performing in vivo bioequivalence studies. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 9. ***Short name: WHO BE guidance*** http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex09.pdf

2. Good clinical laboratory practice (GCLP), WHO on behalf of the Special Programme for Research and Training in Tropical Diseases. Geneva, 2009
Short name: WHO GCLP
https://www.who.int/tdr/publications/documents/gclp-web.pdf

3. Guidelines for good clinical practice for trials on pharmaceutical products. WHO Technical Report Series, No. 850, 1995 (pp. 97–137). ***Short name: WHO GCP***
http://apps.who.int/medicinedocs/en/d/Js5516e/19.11.html

4. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9. ***Short name: WHO TRS 1010, Annex 9***
https://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS1010annex9.pdf?ua=1

5. Handbook – Good Laboratory Practice (GLP): quality practices for regulated non-clinical research and development – Annex I: The OECD Principles on GLP, 2nd ed., 2009. ***Short name: OECD GLP***
http://www.who.int/tdr/publications/documents/glp-handbook.pdf

6. Standards and operational guidance for ethics review of health-related research with human participants. Guidance Document. Geneva, World Health Organization, 2011. ***Short name: WHO Ethics Committee Guidance***
https://www.who.int/ethics/publications/9789241502948/en/

7. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO storage and transport guidance*** or ***TRS 961 Annex 9***
http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

8. Guidelines for the preparation of a contract research organization master file, WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 7.
   Short name: WHO CROMF Guidelines or ***TRS No. 957, Annex 7***
   http://www.who.int/medicines/publications/44threport/en/

9. Glove use information leaflet, Patient Safety, Save lives clean your hands. Geneva, World Health Organization, 2009 (revised). ***Short name: Glove use information leaflet***
   http://www.who.int/gpsc/5may/Glove_Use_Information_Leaflet.pdf

10. WHO guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
    Short name: Annex 5 WHO GDRMP guidance
    http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf