

INVESTIGATOR COMPLIANCE SEARCH FORM

ICON Project Number:	0078-1409	Sponsor Protocol No.:	IM011011
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(if applicable)	Ajith Cy, MB BS, MD, FRCPC / ML # 89297		

Please list all relevant sources of Investigator information, against which this Investigator has been checked.

SOURCE #	SOURCE NAME	SOURCE DATE	WEBLINK	ISSUES IDENTIFIED		
1.	FDA DEBARMENT LIST	04 Apr 2016	http://www.fda.gov/ora/compliance_ref/debar/default.htm	⊠ No	☐ Yes	
2.	CLINICAL INVESTIGATOR INSPECTION LIST (CLIIL) (CDER)	22 Sep 2016	http://www.accessdata.fda.g ov/scripts/cder/cliil/index.cfm	□ No	⊠ Yes	
3.	FDA WARNING LETTERS and RESPONSES	05 Dec 2016	http://www.fda.gov/ICECI/En forcementActions/WarningL etters/default.htm	⊠ No	☐ Yes	
4.	NOTICE OF OPPORTUNITY FOR HEARING (NOOH) – PROPOSAL TO DEBAR	29 Nov 2016	http://www.fda.gov/Regulato ryInformation/FOV Electronic ReadingRoom/ucm143240.h tm	⊠ No	☐ Yes	
5.	ADEQUATE ASSURANCES LIST FOR CLINICAL INVESTIGATORS	24 Apr 2014	http://www.fda.gov/ora/comp liance_ref/bimo/asurlist.htm	⊠ No	☐ Yes	
6.	CLINICAL INVESTIGATORS - DISQUALIFICATION PROCEEDINGS (FDA DISQUALIFIED/RESTRI CTED)	05 Dec 2016	http://www.accessdata.fda.qov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&preview Mode=true&displayAll=true	⊠ No	☐ Yes	
7.	PHS Administrative Actions Listing	05 Dec 2016	http://ori.hhs.gov/misconduct /AdminBulletinBoard.shtml	⊠ No	☐ Yes	
8.	Clinical Investigator Inspection List (CBER)	27 Oct 2016	http://www.fda.gov/Biologics BloodVaccines/GuidanceCo mplianceRegulatoryInformati on/ComplianceActivities/ucm 195364.htm	⊠ No	☐ Yes	
9.	HHS/OIG/ EXCLUSIONS DATABASE SEARCH/ FRAUD	07 Nov 2016	http://exclusions.oig.hhs.gov	⊠ No	☐ Yes	
10.	HHS/OIG Corporate Integrity Agreements/Watch List	18 Nov 2016	http://oig.hhs.gov/complianc e/corporate-integrity- agreements/cia- documents.asp	⊠ No	☐ Yes	

SST002-SOP-F01/Version 1.0/Effective 28 April 2014

(Ref. SST002-SOP)

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11.	SAWSYSTEM FOR AWARD MANAGEMENT	11 Nov 2016	https://www.sam.gov/portal/ public/SAM	⊠ No	☐ Yes
12.	LIST OF SPECIALLY DESIGNATED NATIONALS	02 Dec 2016	http://www.treasury.gov/reso urce-center/sanctions/SDN- List/Pages/default.aspx	⊠ No	☐ Yes
13.	World Check (Only for PI)	06 Dec 2016	http://www.truthtechnologies .com/	⊠ No	☐ Yes

If issues are identified (Yes checked above), please provide additional details. Details may be printed and attached.

SOURCE #	DATE OF INSPECTION ACTION	DESCRIPTION OF FINDINGS
NA	Kim Alexander Papp, MD, PhD, FRCPC	Was also searched as Kim Alexander, Alexander Papp and Kim Papp.
NA	Ajith Cy, MB BS, MD, FRCPC	Was also searched as Ajith Chakkittakandiyil.
2	15 March 2004 Kim Alexander Papp, MD, PhD, FRCPC ID # 416907 DA / NAI	DA - Data Audit: An inspection in which the focus is on verification of study data. NAI - No Action Indicated. No objectionable conditions or practices were found during the inspection.
2	05 May 2014 Kim Alexander Papp, MD, PhD, FRCPC ID # 416907 DA / NAI / 00	 DA - Data Audit: An inspection in which the focus is on verification of study data. NAI - No Action Indicated. No objectionable conditions or practices were found during the inspection. 00 - No deficiencies noted

Search Performed E	3y:
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Printed	Cianatura	Date:
Name:	Signature:	Date.

Sharon Jerome

Sharon Jerome 06 Dec 2016 08:51:037+0000

I approve this document as author.

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Second Review / QC:

Pramodh Manganam Siddiah Babu

Pramodh Manganamsiddiahbabu 06 Dec 2016 09:03:019+0000

I approve this document.

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Clinical Investigator Inspection Search

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<u>+</u>
EMAIL (MAILTO:?SUBJECT=CLINICAL INVESTIGATOR INSPECTION SEARCH&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/CLIIL/INDEX.CFM? FUSEACTION=SEARCH.SEARCH)

Search Results for 'Papp' in all Fields

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Investi	Investigator Information Inspection Information										
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