

INVESTIGATOR COMPLIANCE SEARCH FORM

ICON Project Number:	9002-0472	Sponsor Protocol No.:	B7981005
Principal Investigator Name:	Bruce Salzberg	Address:	Atlanta Gastroenterology Consultants.net 4395 Johns Creek Parkway Suwanee, GA 30024, USA
Medical License Number (if applicable)	29775		

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	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
2.	CLINICAL INVESTIGATOR INSPECTION LIST (CLIIL) (CDER)	22 Sep 2016	http://www.accessdata.fda.gov/scripts/cder/cliil/index.cfm	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes
3.	FDA WARNING LETTERS and RESPONSES	07 Dec 2016	http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
4.	NOTICE OF OPPORTUNITY FOR HEARING (NOOH) – PROPOSAL TO DEBAR	29 Nov 2016	http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/ucm143240.htm	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
5.	ADEQUATE ASSURANCES LIST FOR CLINICAL INVESTIGATORS	24 Apr 2016	http://www.fda.gov/ora/compliance_ref/bimo/asurlist.htm	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
6.	CLINICAL INVESTIGATORS – DISQUALIFICATION PROCEEDINGS (FDA DISQUALIFIED/RESTRICTED)	05 Dec 2016	http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
7.	PHS Administrative Actions Listing	07 Dec 2016	http://ori.hhs.gov/misconduct/AdminBulletinBoard.shtml	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
8.	Clinical Investigator Inspection List (CBER)	27 Oct 2016	http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
9.	HHS/OIG/ EXCLUSIONS DATABASE SEARCH/	07 Nov 2016	http://exclusions.oig.hhs.gov	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes

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10.	HHS/OIG Corporate Integrity Agreements/Watch List	18 Nov 2016	http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
11.	SAM/SYSTEM FOR AWARD MANAGEMENT	11 Nov 2016	https://www.sam.gov/portal/public/SAM	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
12.	LIST OF SPECIALLY DESIGNATED NATIONALS	02 Dec 2016	http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
13.	World Check (Only for PI)	07 Dec 2016	https://sentinel.truthtechnologies.com	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
14.	DMC Check	29 Nov 2016	http://ecf12.pfizer.com/sites/clinicaloversightcommittee/default.aspx	<input checked="" type="checkbox"/> No	<input type="checkbox"/> 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
2	22 March 2016 Bruce Salzberg MD ID # 391968 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 [n/a]
2	17 November 2008 Bruce Salzberg, MD ID # 391968 DA / VAI / 05	DA - Data Audit: An inspection in which the focus is on verification of study data VAI - Voluntary Action Indicated. Objectionable conditions were found but the problems do not justify further regulatory action. Any corrective action is left to the investigator to take voluntarily. 05 - Failure to follow investigational plan [21 CFR 312.60]

Search Performed By:

Printed Name:	Signature:	Date:
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Pramodh Manganam Siddiah Babu

Pramodh Manganamsiddiahbabu 08 Dec 2016 05:08:049+0000

I approve this document as author.

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Clinical Investigator Inspection Search

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Investigator Information

Inspection Information

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391968	salzberg, bruce a MD	Atlanta Gastroenterology Associates	5671 Peachtree Dunwoody Rd Ne Ste 600	Atlanta	GA	USA	30342	11/17/08	DA	VAI	05

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