

Biostatistics statement

Ref.: ADAPT study
internal CIP ID: Ada-UC-08-101
ClinicalTrial.gov number: NCT 00781638

The statistical methods of this study were reviewed by Regina Khrakovsky from
TechnoStat, 34 Jerusalem Rd., Beit Gamla-Bldg B, 5th Floor, Raanana, 4350108 Israel

IA.P.  01 DEC 2015

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**Open Uncontrolled Investigation to Assess the Efficacy and
Safety of Adacolumn® Granulocytes, Monocytes/Macrophage
Apheresis Device in Children and Adolescents with
Active Ulcerative Colitis**

Clinical Investigation Report

Issued: 31 October 2012
Final Version

**THIS INVESTIGATION WAS PERFORMED IN ACCORDANCE WITH ISO14155
AND ICH GUIDELINE**

Confidentiality Statement:

The information provided in this document is strictly confidential and is available for review to investigators, potential investigators and appropriate Ethics Committees or Institutional Review Boards. No disclosure should take place without written authorization from the Sponsor, except to the extent necessary to obtain informed consent.

CLINICAL INVESTIGATION REPORT

Title: Open Uncontrolled Investigation to Assess the Efficacy and Safety of Adacolumn® Granulocytes, Monocytes/Macrophage Apheresis Device in Children and Adolescents with Active Ulcerative Colitis

CIP ID: Ada-UC-08-101

Indication: Active Ulcerative Colitis with Pediatric Ulcerative Colitis Activity Index (PUCAI) of 35-64 (moderate)

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First approved CIP: Version 1.0 (31 July 2008)

Amendments to CIP: Version 1.1 (17 November 2008)
Version 1.2 (25 June 2010)

First Patient In 09 March 2009

Last Patient Screened 17 November 2010

Last Patient Out 31 January 2012

SIGNATURES


Title: Open Uncontrolled Investigation to Assess the Efficacy and Safety of Adacolumn® Granulocytes, Monocytes/Macrophage Apheresis Device in Children and Adolescents with Active Ulcerative Colitis

Device: Adacolumn® granulocytes, monocytes/macrophage apheresis device

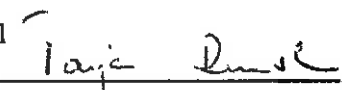
CIP ID: Ada-UC-08-101

The undersigned have read this final study report and hereby confirm that, to the best of their knowledge, it accurately describes the conduct and the results of the clinical investigation.

Martin Bauer, MD
Head of Clinical Development & Operations
Otsuka Frankfurt Research Institute GmbH


Signature Date 10 Dec 2012


Coordinating Investigator:
Tarja Ruuska, MD, PhD
Tampere University Medical Hospital


Signature Date 30 November 2012

Statistician:
~~Sergey Goichman~~ Regina Khakovsky
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Signature Date 2 January 2013

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Signature Date 04 December 2012