

## 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. [Signature] 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)

**Sponsor:** Otsuka Frankfurt Research Institute GmbH  
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**Principal Investigator:** Tarja Ruuska, MD, PhD  
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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

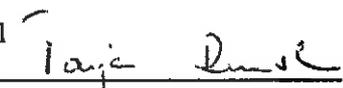
**CIP ID:** Ada-UC-08-101

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

  
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Signature Date 10 Dec 2012

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

  
\_\_\_\_\_  
Signature Date 30 November 2012

**Statistician:**  
~~Sergey Goichman~~ Regina Kharkovsky  
TechnoSTAT Ltd.

  
\_\_\_\_\_  
Signature Date 2 January 2013

**Author of the Report:**  
Evelyn Groot, PhD  
Factory CRO for Medical Devices

  
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Signature Date 04 December 2012