# Ongoing Clinical Trials

This section provides information for researchers on clinical trials being in progress in their field throughout the world. The list of trials described herein is by no means inclusive, and the publisher is not responsible for any data given.

Please use the special questionnaire at the end of this section to submit information on a new trial.

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<thead>
<tr>
<th>Title of Trial</th>
<th>Lead Investigator</th>
<th>Study Design</th>
<th>Current Status</th>
<th>Sponsor</th>
<th>Contact</th>
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<tbody>
<tr>
<td><strong>Colorectal</strong></td>
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</table>
| **CAPP 2**     | Prof. John Burn   | Phase II, multicenter (33 centers), prospective, double-blind trial | Ongoing (start January 1999; end December 2006) | MRC, Cancer Research UK, Bayer AG, National Starch and Chemical Company | Ms. Gail Barker  
University of Newcastle, UK  
Newcastle upon Tyne, UK  
Tel.: +44 191 241 8613  
E-Mail: gail.barker@ncl.ac.uk |
| Randomized controlled trial of colorectal polyp and cancer prevention using aspirin and resistant starch in carriers of hereditary nonpoly-posis colon cancer (HNPCC) | University of Newcastle, UK | Factorial design  
Regimen: Aspirin 600 mg, resistant starch 30 g for 2-4 years  
Control: Placebo/active  
Endpoint: Colorectal neoplasm  
Patient population: Gene carriers of hereditary HNPCC n=1000 |             |         |         |
| **COLOR II**   | Prof. H.J. Bonjer | Multicenter (30 centers), prospective, randomized, open trial | Ongoing (start January 2003; end January 2008) | Ethicon Endosurgery (Europe) | Prof. H.J. Bonjer  
Department of Surgery  
Erasmus Medisch Centrum Rotterdam, The Netherlands  
Rotterdam, The Netherlands  
Tel.: +31 10 463 4735  
Fax: +31 10 463 5058  
E-Mail: bonjer@hlkd.azr.nl |
| A randomized clinical trial comparing laparoscopic and open surgery for rectal cancer | Erasmus Medisch Centrum Rotterdam, The Netherlands  
Hospital I Clinic Provincial de Barcelona, Spain | Control: Active controls  
Endpoint: Locoregional recurrence 3 years postoperative  
Patient population: Patients with nonmetastatic rectal cancer n=1275 |             |         |         |
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<tr>
<th>Title of Trial</th>
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<tr>
<td>DaCHS - Prevention of colorectal carcinoma: The role of screening</td>
<td>Prof. Dr. H. Brenner, Deutsches Zentrum für Alternsforschung, Heidelberg, Germany</td>
<td>Independent, case-control trial, n=600</td>
<td>Ongoing (start January 2003; end of recruitment December 2007)</td>
<td>DZAF (Deutsches Zentrum für Alternsforschung)</td>
<td>Dr. Christoph Seiler, MSc Heidelberg, Germany</td>
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<tr>
<td>Colon-J-pouch versus transverse coloplasty pouch: A randomized controlled trial comparing functional results after rectum resection and different reconstructions</td>
<td>PD Dr. Kaspar Z’graggen, Klinik Beau-Site, Berne, Switzerland</td>
<td>Multicenter, prospective, randomized, open trial</td>
<td>Ongoing</td>
<td>Dr. Christoph Seiler, MSc Heidelberg, Germany</td>
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<tr>
<td>Prospectively randomized study comparing function and quality of life after a coloplasty/low colorectal anastomosis or coloanal anastomosis versus a straight anastomosis or a colonic J-pouch low colorectal or coloanal anastomosis</td>
<td>Victor W. Fazio, MD, Feza Remzi, MD Cleveland Clinic Foundation, Cleveland, Ohio, USA</td>
<td>Prospective, randomized trial</td>
<td>Follow-up (start June 2004; end June 2006)</td>
<td>Dr. Masarat Zutshi, Cleveland, Ohio, USA</td>
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<tr>
<td>Influence of two different resection techniques of liver metastases from colorectal cancer on hematogenous tumor cell dissemination</td>
<td>Jürgen Weitz, MD, Department of Surgery, University of Heidelberg, Germany</td>
<td>Multicenter (3 centers), prospective open trial</td>
<td>Ongoing</td>
<td>Prof. M.W. Büchler</td>
<td>Dr. Christoph Seiler, MSc Heidelberg, Germany</td>
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**ISRCTN Nr.:** 78983587

**ISRCTN No.:** 45066244
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<tr>
<th>Title of Trial</th>
<th>Lead Investigator</th>
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<tr>
<td>InTACT: Interdisciplinary trial of adjuvant colon cancer treatment</td>
<td>Prof. Dr. W. Hohenberger, University Hospital Erlangen, Germany</td>
<td>Phase III, multicenter, prospective, investigator-blind trial&lt;br&gt;&lt;br&gt;&lt;strong&gt;Regimen:&lt;/strong&gt; 24-hour infusion with 5-FU (2,000 mg/m²) ; folinic acid (500 mg/m²) once weekly for 6 months (adjuvant treatment arm)&lt;br&gt;&lt;br&gt;&lt;strong&gt;Control:&lt;/strong&gt; Adjuvant therapy versus surgery (quality controlled) alone&lt;br&gt;&lt;br&gt;&lt;strong&gt;Endpoint:&lt;/strong&gt; Survival, disease-free survival&lt;br&gt;&lt;br&gt;&lt;strong&gt;Patient population:&lt;/strong&gt; Patients with stage III (UICC) colon cancer complete resection (R0); n=240&lt;br&gt;&lt;br&gt;&lt;strong&gt;Additional information:&lt;/strong&gt; Interim analysis after randomization of 120 patients</td>
<td>Follow-up (start October 2001; end October 2006)</td>
<td>Dr. Bertram Reingruber, Erlangen, Germany&lt;br&gt;Dr. Bertram Reingruber&lt;br&gt;Erlangen, Germany&lt;br&gt;Tel.: +49 9131 853 32 96&lt;br&gt;Fax: +49 9131 853 61 44&lt;br&gt;E-Mail: <a href="mailto:bertram.reingruber@stud.uni-erlangen.de">bertram.reingruber@stud.uni-erlangen.de</a></td>
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<td>ROMIC: Role of ovarian metastasis in colorectal cancer</td>
<td>R.M.H. Roumen, MD, Maxima Medical Center Department of Surgery Veldhoven, the Netherlands</td>
<td>Multicenter (12 centers), prospective, unblinded (oophorectomy) trial&lt;br&gt;&lt;br&gt;&lt;strong&gt;Control:&lt;/strong&gt; Patients who do not undergo oophorectomy&lt;br&gt;&lt;br&gt;&lt;strong&gt;Endpoint:&lt;/strong&gt; 3-year disease-free survival&lt;br&gt;&lt;br&gt;&lt;strong&gt;Patient population:&lt;/strong&gt; Postmenopausal women with colorectal cancer without evidence of metastatic disease&lt;br&gt;&lt;br&gt;N=1000&lt;br&gt;&lt;br&gt;&lt;strong&gt;Additional information:&lt;/strong&gt; Incidence of micrometastases in ovaria of colorectal cancer patients and prevention of future Krukenberg tumors</td>
<td>Ongoing (start 2003; end 2007)</td>
<td>R.M.H. Roumen, MD, Veldhoven, the Netherlands&lt;br&gt;R.M.H. Roumen, MD&lt;br&gt;Veldhoven, the Netherlands&lt;br&gt;Tel.: +31 40 8888 556&lt;br&gt;Fax: +31 40 8888565&lt;br&gt;E-Mail: <a href="mailto:r.roumen@mmc.nl">r.roumen@mmc.nl</a></td>
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Pancreatic

**Neoadjuvant chemoradiation in pancreatic cancer**
Prof. Dr. W. Hohenberger
University Hospital Erlangen, Germany
Prof. Dr. G. Grabenbauer
University Hospital Erlangen, Germany

Multicenter, prospective, nonrandomized trial

**Patient population:** Patients with potentially resectable carcinoma of the pancreatic head
n=254

**Additional information:** Pilot project finished, new trial with gemcitabine and cis-platin as radiosensitizers

Ongoing (start June 2003; 42 patients recruited as of February 2006)

**PD Dr. T. Meyer**
Erlangen, Germany
Tel.: +49 9131 853 32 96
Fax: +49 9131 853 65 95
E-Mail: Thomas.meyer@chir.imed.uni-erlangen.de

**PD Dr. T. Brunner**
Erlangen, Germany
E-Mail: thomas.brunner@strahlen.imed.uni-erlangen.de

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**GEM-CAP**
Trial comparing gemcitabine alone or in combination with capecitabine for the treatment of patients with advanced pancreatic ductal adenocarcinoma

Professor J.P. Neoptolemos
Department of Surgery, University of Liverpool, UK

Phase III, multicenter, randomized trial

**Regimen:** Patients treated with gemcitabine alone or a combination of gemcitabine and capecitabine for 12 weeks; those responding to treatment or with stable disease receive a further 12 weeks of treatment

**Primary endpoint:** One-year survival

**Secondary endpoint:** Quality of life; median and two-year survival; toxicity; objective response rate

**Patient population:** Patients with histological or cytological evidence of locally advanced / metastatic carcinoma of the pancreas not amenable to curative surgery / radiotherapy; n=508

Ongoing (closed to recruitment as target accrual has been reached)

**Ms. Claire Davies**, Coordinator
Liverpool, UK
Tel.: +44 151 794 8933
Fax. 144 151 794 8930
E-Mail: cldavies@liverpool.ac.uk

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**ESPAC-2**
Adjuvant therapies in resectable pancreatic cancer

Dr. C.H.J. van Eijck
Erasmus Medisch Centrum Rotterdam, The Netherlands

Phase III, prospective trial; patients randomized into two groups

**Control:** Surgery alone versus intra-arterial chemotherapy and radiotherapy

**Endpoint:** 2-year survival

**Patient population:** n=100

Ongoing

**Dr. C.H.J. van Eijck**
Rotterdam, The Netherlands
Tel.: +31 104 633 854
E-Mail: c.vaneijck@erasmusmc.nl
### Ongoing Clinical Trials (continued)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Principal Investigator</th>
<th>Institution</th>
<th>Study Description</th>
<th>Phase</th>
<th>Sponsor</th>
<th>Contact Information</th>
</tr>
</thead>
</table>
| **ESPAC-3(v2)** | Prof. J.P. Neoptolemos | Department of Surgery, University of Liverpool, UK | Adjuvant chemotherapies in resectable pancreatic cancer | International multicenter (130 centers) trial; patients with pancreatic ductal adenocarcinoma randomized into one of two groups (gemcitabine; 5-FU and folinic acid) and patients with ampullary or other tumors of the pancreas randomized into one of three groups (gemcitabine; 5-FU and folinic acid, and observation) | Recruitment phase (end 2005) | Cancer Research UK | Mrs. Emily Owen, Coordinator Liverpool, UK  
Tel.: +44 151 794 8932  
Fax: +44 151 794 8930  
E-Mail: e.owen@liverpool.ac.uk |
| **Miscellaneous** | Priv. Doz. C.-T. Germer | Department of Surgery, University Hospital BF Berlin, Germany | Multicenter randomized trial for laser-induced thermotherapy of colorectal liver metastases | Phase III, multicenter (6 centers), randomized trial  
Control: Surgical liver resection  
Endpoint: Patient survival, quality of life/mortality  
Patient population: Patients with 4 or fewer liver metastases, diameter 4 cm or smaller and with no signs of extrahepatic malignant disease | Recruitment phase (start August 2000; end July 2007) | BMBF | Prov. Doz. C.-T. Germer  
Berlin, Germany  
Tel.: +49 30 8445 2543  
Fax: +49 30 8445 2740  
E-Mail: germer@ukbf.fu-berlin.de |
### Inflammatory Bowel Disease

<table>
<thead>
<tr>
<th>Study Description</th>
<th>Phase</th>
<th>Sponsor</th>
<th>Contact Information</th>
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</thead>
</table>
| Multicenter, randomized, double-blind, placebo-controlled retreatment study of  | Ongoing | Berlex | Anna Williford, RN
| sargramostim (Leukine®) in patients with active Crohn’s Disease and prior      |       |        | Louisville, Ky., USA
| treatment response to sargramostim (Berlex protocol 308180)                     |       |        | Tel.: +1 502 583 0880
|                                                                                 |       |        | Fax: +1 502 583 3307
|                                                                                 |       |        | E-Mail: aowill01@gwise.louisville.edu                                               |
| Open label trial of Leukine® (sargramostim), a recombinant granulocyte          | Ongoing | Berlex | Anna Williford, RN
| macrophage colony stimulating factor (GM-CSF) in Crohn’s disease                |       |        | Louisville, Ky., USA
|                                                                                 |       |        | Tel.: +1 502 583 0880
|                                                                                 |       |        | Fax: +1 502 583 3307
|                                                                                 |       |        | E-Mail: aowill01@gwise.louisville.edu                                               |
## Surgical Infection / Sepsis

<table>
<thead>
<tr>
<th>Trial</th>
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<th>Principal Investigator</th>
<th>Institution</th>
<th>Sponsorship</th>
<th>Endpoint</th>
<th>Patient Population</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td><strong>PANTER</strong></td>
<td>Minimally invasive 'step-up approach' vs. maximal necrosectomy in patients with acute necrotizing pancreatitis</td>
<td>Prof. H.G. Gooszen</td>
<td>Head, Department of Surgery University Medical Center Utrecht, The Netherlands</td>
<td>Chairman Dutch Acute Pancreatitis Study Group</td>
<td>Multicenter (20 centers of the Dutch Acute Pancreatitis Study Group), prospective, non-blinded, active-controlled trial</td>
<td>Patients are randomized between A) Maximal necrosectomy by laparotomy with continuous postoperative lavage and B) CT-guided percutaneous or endoscopic transgastric drainage, if necessary followed by videoendoscopic assisted retroperitoneal debridement (VARD)</td>
<td><strong>Endpoint</strong>: Total mortality and major morbidity</td>
</tr>
<tr>
<td><strong>PROPATRIA</strong></td>
<td>Multicenter, randomized, blinded, placebo-controlled trial of probiotic prophylaxis in predicted severe acute pancreatitis</td>
<td>Prof. H.G. Gooszen</td>
<td>Head, Department of Surgery University Medical Center Utrecht, The Netherlands</td>
<td>Chairman Dutch Acute Pancreatitis Study Group</td>
<td>Investigator-initiated, multicenter, double-blind, placebo-controlled trial</td>
<td>Patients randomly assigned to receive either live multispecies probiotics (6 strains, Ecologica 641) or placebo for 4 weeks by nasojejunal tube. Treatment started within 72 hours of onset of abdominal pain</td>
<td><strong>Regimen</strong>: Patients randomly assigned to receive either live multispecies probiotics (6 strains, Ecologica 641) or placebo for 4 weeks by nasojejunal tube. Treatment started within 72 hours of onset of abdominal pain</td>
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### Miscellaneous

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<thead>
<tr>
<th>Trial</th>
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<th>Endpoint</th>
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<tbody>
<tr>
<td><strong>Mesh plug versus Lichtenstein, prospective and randomized study</strong></td>
<td></td>
<td>Dr. A. Wildisen</td>
<td>Kantonales Spital Sursee-Wolhusen, Switzerland</td>
<td><strong>Hernia recurrence</strong></td>
<td>n=900</td>
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<tr>
<td>Trial Name</td>
<td>Principal Investigator</td>
<td>Institution</td>
<td>Study Design</td>
<td>Control</td>
<td>Endpoint</td>
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<td>POVATI: Postsurgical pain outcome in patients with vertical and transverse abdominal incision: A randomized controlled equivalence trial</td>
<td>Prof. M.W. Büchler</td>
<td>Department of Surgery, University of Heidelberg, Germany</td>
<td>Single center, prospective, patient-blind trial, n=200</td>
<td>Ongoing Prof. M.W. Büchler</td>
<td>Dr. Christoph Seiler, MSc Heidelberg, Germany</td>
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<tr>
<td>LAPCON: Total laparoscopic versus conventional ileoanal pouch procedure: a randomized controlled trial</td>
<td>Prof. M.W. Büchler</td>
<td>Department of Surgery, University of Heidelberg, Germany</td>
<td>Single center, prospective, open trial</td>
<td>Control: Laparoscopic versus conventional ileoanal pouch procedure Endpoint: Intraoperative blood loss Patient population: Patients with familial polyposis or ulcerative colitis, scheduled for elective proctocolectomy with ileoanal pouch</td>
<td>Dr. Christoph Seiler, MSc Heidelberg, Germany</td>
</tr>
<tr>
<td>INSECT: Interrupted or continuous slowly absorbable suture evaluation of abdominal closure techniques</td>
<td>Prof. M.W. Büchler</td>
<td>Department of Surgery, University of Heidelberg, Germany</td>
<td>Multicenter, prospective, open trial</td>
<td>Control: Comparison of three techniques Endpoint: Frequency of abdominal hernias after 12 months and 3 years Patient population: Patients who are planned to undergo an elective abdominal operation</td>
<td>BBD-Aesculap Dr. Christoph Seiler, MSc Heidelberg, Germany</td>
</tr>
<tr>
<td>CLIVIT: Clips vs. Ligatures. A multicenter randomized controlled trial</td>
<td>Prof. M.W. Büchler</td>
<td>Department of Surgery, University of Heidelberg, Germany</td>
<td>Multicenter, prospective, open trial</td>
<td>Control: Comparison of two techniques to control vessels in thyroid surgery Endpoint: Time of resection Patient population: Patients who are planned to undergo an elective bilateral thyroid resection</td>
<td>BBD-Aesculap Dr. Christoph Seiler, MSc Heidelberg, Germany</td>
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<td>Ongoing Clinical Trials (continued)</td>
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<tr>
<td><strong>EUROPAC 2</strong></td>
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<tr>
<td>Double-blind randomized controlled trial to investigate the efficacy of Antox and MGCT for the treatment of hereditary pancreatitis and idiopathic chronic pancreatitis</td>
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<tr>
<td><strong>Phase III, double-blind, placebo-controlled randomized trial</strong></td>
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<td><strong>Regimen:</strong> Antioxidants for 1 year</td>
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<td><strong>Control:</strong> Placebo</td>
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<td><strong>Primary endpoint:</strong> Reduction in the number of days of pancreatic pain</td>
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<td><strong>Secondary endpoint:</strong> Analgesic use; hospital admissions; quality of life scores</td>
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<td><strong>Patient population:</strong> Patients (5-40 years old) with hereditary pancreatitis or idiopathic chronic pancreatitis, registered with EUROPAC, having characteristic pain that is either intermittent or continuous</td>
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<td><strong>Recruitment (start 2006)</strong></td>
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<td><strong>Recruitment</strong></td>
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<tr>
<td><strong>EUROPAC Study Coordinator</strong></td>
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<td>Michael G.T. Raraty, MB, BS, PhD, FRCS</td>
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<tr>
<td>Liverpool, UK</td>
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<td>Tel.: +44 151 706 4170</td>
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<td>Fax: +44 151 706 5826</td>
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<tr>
<td>E-Mail: <a href="mailto:mraraty@liv.ac.uk">mraraty@liv.ac.uk</a> / <a href="mailto:europac@liv.ac.uk">europac@liv.ac.uk</a></td>
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<thead>
<tr>
<th><strong>Open, randomized, multicenter, phase IIIb study</strong></th>
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<td>for 5 years to assess long-term efficiency and tolerability of esomeprazole compared to laparoscopic anti-reflux surgery in adult subjects with chronic gastroesophageal reflux disease</td>
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<tr>
<td><strong>Phase IIIb, multicenter (60 centers), prospective, open trial</strong></td>
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<tr>
<td><strong>Regimen:</strong> 20-40 mg esomeprazole for 5 years</td>
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<tr>
<td><strong>Control:</strong> Surgery</td>
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<tr>
<td><strong>Endpoint:</strong> Time to treatment failure</td>
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<tr>
<td><strong>Patient population:</strong> Patients suffering from confirmed gastroesophageal reflux disease for more than 6 months n=550</td>
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<td><strong>Follow-up (end June 2008)</strong></td>
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<td><strong>Follow-up</strong></td>
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<tr>
<td><strong>Astra Zeneca</strong></td>
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<tr>
<td>Dr. Christoph Seiler, MSc</td>
</tr>
<tr>
<td>Heidelberg, Germany</td>
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<tr>
<td>Tel.: +49 6221 56 6986</td>
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<tr>
<td>Fax: +49 6221 56 6988</td>
</tr>
<tr>
<td>E-Mail: <a href="mailto:christoph_seiler@med.uni-heidelberg.de">christoph_seiler@med.uni-heidelberg.de</a></td>
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<td><a href="http://www.sdgc.de">www.sdgc.de</a></td>
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</table>
Questionnaire for Trial Submission

To submit information on a clinical trial for publication in the 'Ongoing Clinical Trials' section, please complete this short questionnaire.

1) Title of study (in full)


2) Lead investigator

Title:

Name:

Affiliation:

3) Field of study

Please indicate one or more of the following categories:

☐ Oncology  ☐ Inflammatory Bowel Disease
☐ Motility  ☐ Surgical Infection/Sepsis  ☐ Miscellaneous

Other (please specify):

4) Study phase (drug trials only)

Please indicate one of the following categories:

☐ Phase I  ☐ Phase II  ☐ Phase III  ☐ Phase IV
☐ Independent (investigator initiated)

5) Study design

☐ Multicenter  ☐ Single center (please indicate as appropriate)
If multicenter, please state how many centers are involved:

☐ Prospective  ☐ Retrospective (please indicate as appropriate)
If prospective, level of randomization (e.g. single blind, double blind, investigator-blind):

Controls (i.e. placebo-, active-, etc.):

Cross-over design (one-way, two-way, etc.):

Duration of therapy (if applicable):

Dosing regimen (if applicable):

Primary study endpoint:

Other information on study design (please include any other details that might be relevant):

6) Patients

Number of patients (planned):

Patient population (e.g. patients with mild UC previously controlled on . . .):

7) Current status of study

Start date:

Estimated end date:

Status (please indicate as appropriate):

☐ Development  ☐ Recruitment  ☐ Ongoing
☐ LPO  ☐ Analysis in progress

Publication

Abstract submitted to:

Manuscript submitted to:

8) Sponsor

9) Contact for further information:

Name:

Address:

Telephone:

Fax:

E-Mail:

Please return the completed questionnaire as soon as possible to the Section Editor:

Susan Galandiuk, MD
Department of Surgery
School of Medicine
University of Louisville
Louisville, KY 40292, USA
Tel.: +1 502 852 5442
Fax: +1 502 852 8915

or contact:

S. Karger AG
Attn.: Ms. Yvonne Rebmann
Allschwilerstrasse 10
PO Box
CH-4009 Basel
Tel.: +41 61 306 13 51
Fax: +41 61 306 12 34
E-Mail: y.rebmann@karger.ch