Supplementary Online Content


**eMethods.** Institutional Review Boards for CIFLOTIII/10IA02 and CIFLOTIII/10IA04

**eTable.** Clinical Response in the Clinical Intention-to-Treat Population

This supplementary material has been provided by the authors to give readers additional information about their work.

© 2016 American Medical Association. All rights reserved.
**Institutional Review Board CIFLOTIII/10IA02**

**United States**

- The Central IRB used in the United States for this study is:

  Copernicus Group IRB  
  One Triangle Drive, Suite 100 Research Triangle Park, 
  North Carolina 27709  
  United States  
  Chair: Glenn C. Veit, JD DIP

- The Local IRB/EC used in the United State is listed below by site:

<table>
<thead>
<tr>
<th>Investigator(s)</th>
<th>Site #</th>
<th>Name, Address, Chair (if applicable) of IRB/IEC</th>
</tr>
</thead>
</table>
| Simon I. Angeli, MD   | 028    | Human Subjects Research Office (IRB)  
  1500NW 126Avenue  
  Room 1002, 10th Floor  
  East Wing  
  Miami, FL 33136  
  United States  
  Chair: Thomas Sick, PhD |
| Steven L. Goudy, MD   | 057    | Vanderbilt University Human Research Protections Program  
  1313 21st Avenues South  
  504 Oxford House  
  Nashville, Tennessee 37232-4315  
  United States  
  Chair: Saralyn Williams, MD |
| James Sidman, MD      | 058    | Children’s Hospitals and Clinics of Minnesota  
  2525 Chicago Avenue S  
  Minneapolis, Minnesota 55404  
  United States  
  Chair: Donald Brunnquell, PhD |
| Hae-Ok Ana Kim, MD    | 039    | The New York Eye and Ear Infirmary IRB  
  310 East 14th Street  
  New York, New York 10003  
  United States  
  Chair: Joseph B. Walsh, MD |
| Ron Mitchell, MD      | 050    | University of Texas Southwestern Medical Center Institutional Review Board  
  5323 Harry Hines Boulevard  
  Dallas, Texas 75390-8843  
  United States  
  Chair: John Sadler, MD |
| Tulio A. Valdez, MD   | 053    | Institutional Review Board Connecticut Children’s Medical Center  
  282 Washington Street  
  Harford, Connecticut 06106  
  United States  
  Chair: Francis J. DiMario, MD, CIP |
| Richard J.H. Smith, MD| 054    | Western Institutional Review Board  
  3535 7th Avenue SW  
  Olympia, Washington 08502  
  United States  
  Chair: Paul Newton, JD |

© 2016 American Medical Association. All rights reserved.
<table>
<thead>
<tr>
<th>Investigator(s)</th>
<th>Site #</th>
<th>Name, Address, Chair (if applicable) of IRB/IEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ellen Mandel, MD</td>
<td>067</td>
<td>University of Pittsburgh IRB</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hieber Building</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Suite 106</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3500 Fifth Avenue</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pittsburgh, Pennsylvania 15213</td>
</tr>
<tr>
<td></td>
<td></td>
<td>United States</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chair: Richard Guido, MD, CIP</td>
</tr>
<tr>
<td>Kevin Pereira, MD</td>
<td>070</td>
<td>Human Research Protections Office Institutional Review Board</td>
</tr>
<tr>
<td></td>
<td></td>
<td>800 West Baltimore Street</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Suite 100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Baltimore, Maryland 21201</td>
</tr>
<tr>
<td></td>
<td></td>
<td>United States</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chair: Robert Rosenthal, MD</td>
</tr>
</tbody>
</table>

Spain
- The Central IRB/EC used by all sites in Spain:

Comite Etico de Investigacion Clinica
Hospital Universitari Vall d’Hebron
Passeig Vall d’Hebron s/n
08035 Barcelona
Spain
Chair: Dra. Mª del Puy Goyache Goñi

Czech Republic
- The Local IRB/ECs used in the Czech Republic are listed below by site:

<table>
<thead>
<tr>
<th>Investigator(s)</th>
<th>Site #</th>
<th>Name, Address, Chair (if applicable) of IRB/IEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prim MUDr. Karel Pokorný, PhD</td>
<td>112</td>
<td>Ethics Committee of the County Hospital in Pardubice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kyjevská 44</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pardubice 532 03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Czech Republic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chair: Jin Vortel, MD</td>
</tr>
<tr>
<td>Prof. Viktor Chrobok, MD, PhD</td>
<td>111</td>
<td>Ethics Committee Of The Teaching Hospital in Hradec Králové</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sokolská 581</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hradec Králové 500 05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Czech Republic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chair: Jin Vortel, MD</td>
</tr>
<tr>
<td>Daniel Groh, MD, PhD</td>
<td>113</td>
<td>Ethics Committee Of The Teaching Hospital in Motol V Úvalu 84</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prague 5 150 06</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Czech Republic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chair: Vratislav Smeihaus, MD</td>
</tr>
</tbody>
</table>

Denmark
- The Local IRB/EC used by the site in Denmark:

De Videnskabsetiske Komiteer for Region Hovedstaden
Regionsgården
Kongens Vaenge 2
Finland

The Local IRB/EC used by the site in Finland:

Pirkanmaan Sairaanohtoioirin Eettinen Toimikunta
PL 2000
Biokatu 10
FM 5.3. Krs., Tiedekeskus Tampere 33521
Finland
Chair: Professor Amos Pasternack

Sweden

The Local IRB/EC used by all sites in Sweden:

Ethics Committee Lund
Regionala etikprövningsnämnden i Lund
Box 133
(Östra Vallgatan 14/Östervångsvägen 1)
Lund, 22100
Sweden
Chair: Anna Tansjö

South Africa

The Central IRB/EC used by all sites in South Africa:

Pharma-Ethics Independent Ethics Research Committee
123 Amcor Road
Lytelton Manor
Centurion, Pretoria 0157
South Africa
Chair: Dr. C. S. J. Duvenage, MBChB, FCP
Institutional Review Board CIFLOTIII/101A04

United States

- The Central IRB used in the United States for this study is:
  Copernicus Group IRB
  One Triangle Drive, Suite 100 Research Triangle Park,
  North Carolina 27709
  United States
  Chair: Glenn C. Veit, JD DIP

- The Local IRB/EC used in the United States is listed below by site:

<table>
<thead>
<tr>
<th>Investigator(s)</th>
<th>Site #</th>
<th>Name, Address, Chair (if applicable) of IRB/IEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marcus M. Fiechtner, MD</td>
<td>219</td>
<td>Medcenter One Research and Bioethics Committee</td>
</tr>
<tr>
<td></td>
<td></td>
<td>300 North 7th Street</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bismarck, North Dakota, 58501</td>
</tr>
<tr>
<td></td>
<td></td>
<td>United States</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chair: Kathy Smart</td>
</tr>
<tr>
<td>Craig Derkay, MD</td>
<td>234</td>
<td>Eastern Virginia Medical School Institutional Review Board</td>
</tr>
<tr>
<td></td>
<td></td>
<td>721 Fairfax Avenue</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Suite 128</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Norfolk, Virginia 23507</td>
</tr>
<tr>
<td></td>
<td></td>
<td>United States</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chair: Scott Kruger, MD</td>
</tr>
</tbody>
</table>

Canada

- The Central IRB/EC used by all sites in Canada:
  Institutional Review Board Services
  372 Hollandview Trail
  Suite 300
  Aurora, Ontario L4G 0A5
  Canada
  Chair: Dr. McGill

Spain

- The Central IRB/EC used by all sites in Spain:
  Comite Etico de Investigacion Clinica
  Hospital Universitari Vall d’Hebron
  Passeig Vall d’Hebron s/n
  08035 Barcelona
  Spain
  Chair: Dra. Mª del Puy Goyache Goñi
Czech Republic

- The Local IRB/ECs used in the Czech Republic are listed below by site:

<table>
<thead>
<tr>
<th>Investigator(s)</th>
<th>Site #</th>
<th>Name, Address, Chair (if applicable) of IRB/IEC</th>
</tr>
</thead>
</table>
| Lukáš Otruba, MD         | 311    | Ethics Committee of the Teaching Hospital Královské Vinohrady in Prague  
Šrobárova 50  
Prague 10, 100 34  
Czech Republic  
Chair: Jan Pachl, CSc. |
| Jan Kolin, MD            | 312    | Ethics Committee of General Teaching Hospital in Prague  
Na Bojiště 1  
Prague 2, 128 08  
Czech Republic  
Chair: Josef Sedivy, CSc. |
| Martin Světlík, MD       | 313    | Ethics Committee of the Tomáš Bata Memorial District Hospital in Zlin  
Havlíčkovo nábřeží 600  
Zlin 76275  
Czech Republic  
Chair: Josef Dusa, MD      |
| Michaela Máchalová, MD   | 314    | Ethics Committee of the Teaching Hospital in Brno  
Jihlavská 20  
Brno 625 00  
Czech Republic Republic  
Chair: Sarka Kozakova, MBA |
| Jana Boleslavská, MD     | 316    | Ethics Committee of the Teaching Hospital in Ostrava  
17. listopadu 1790  
Ostrava- Poruba 70852  
Czech Republic Republic  
Chair: Ludel Roznovsly, CSc. |

Denmark

- The Local IRB/EC used by the site in Denmark:

De Videnskabsetiske Komiteer for Region Hovedstaden  
Regionsgården  
Kongens Vaenge 2  
Hillerad 3400  
Denmark Chair: Lone Gundelach

Finland

- The Local IRB/EC used by the site in Finland:

Pirkanmaan Sairaanhoitopiirin Eettinen Toimikunta  
PL 2000  
Biokatu 10  
FM 5,3. Krs., Tiedekeskus Tampere 33521  
Finland  
Chair: Professor Amos Pasternack

Sweden

- The Local IRB/EC used by all sites in Sweden:

Ethics Committee Lund  
Regionala etikprövningsnämnden i Lund
South Africa

- The Central IRB/EC used by all sites in South Africa:

Pharma-Ethics Independent Ethics Research Committee
123 Amcor Road
Lyttelton Manor
Centurion, Pretoria 0157
South Africa
Chair: Dr. C. S. J. Duvenage, MBChB, FCP
### eTable. Clinical Response in the Clinical Intention-to-Treat Population

<table>
<thead>
<tr>
<th>Response</th>
<th>Ciprofloxacin plus fluocinolone (n=223)</th>
<th>Ciprofloxacin (n=221)</th>
<th>Fluocinolone (n=218)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success, No. (%)</td>
<td>54 (25.8%)</td>
<td>39 (19.5%)</td>
<td>33 (17.6%)</td>
</tr>
<tr>
<td>Failure, No. (%)</td>
<td>155 (74.2%)</td>
<td>161 (80.5%)</td>
<td>155 (82.4%)</td>
</tr>
<tr>
<td>Missing, No.</td>
<td>14</td>
<td>21</td>
<td>30</td>
</tr>
<tr>
<td>Difference vs ciprofloxacin plus fluocinolone, % (95% CI)</td>
<td>NA</td>
<td>6.3% (-1.8 – 14.5)</td>
<td>8.2% (0.1 – 16.4)</td>
</tr>
<tr>
<td>P value&lt;sup&gt;a&lt;/sup&gt;</td>
<td>NA</td>
<td>0.12</td>
<td>0.04</td>
</tr>
<tr>
<td>Visit 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success, No. (%)</td>
<td>176 (79.6%)</td>
<td>136 (62.4%)</td>
<td>94 (44.3%)</td>
</tr>
<tr>
<td>Failure, No. (%)</td>
<td>45 (20.4%)</td>
<td>82 (37.6%)</td>
<td>118 (55.7%)</td>
</tr>
<tr>
<td>Missing, No.</td>
<td>2</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Difference vs ciprofloxacin plus fluocinolone, % (95% CI)</td>
<td>NA</td>
<td>17.2 (8.8 – 25.7)</td>
<td>35.3% (26.2 – 44.4)</td>
</tr>
<tr>
<td>P value&lt;sup&gt;a&lt;/sup&gt;</td>
<td>NA</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Visit 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success, No. (%)</td>
<td>179 (80.6%)</td>
<td>147 (67.4%)</td>
<td>101 (47.6%)</td>
</tr>
<tr>
<td>Failure, No. (%)</td>
<td>43 (19.4%)</td>
<td>71 (32.6%)</td>
<td>111 (52.4%)</td>
</tr>
<tr>
<td>Missing, No.</td>
<td>1</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Difference vs ciprofloxacin plus fluocinolone, % (95% CI)</td>
<td>NA</td>
<td>13.2 (5.0 – 21.4)</td>
<td>33.0 (24.0 – 42.0)</td>
</tr>
<tr>
<td>P value&lt;sup&gt;a&lt;/sup&gt;</td>
<td>NA</td>
<td>0.002</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Abbreviation: NA, not applicable.
<sup>a</sup>P value is obtained from the χ2 test vs the ciprofloxacin plus fluocinolone treatment group.