# Clinical Trial Protocol

<table>
<thead>
<tr>
<th><strong>Project No:</strong></th>
<th>TMC120</th>
<th><strong>Non-Proprietary name:</strong></th>
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<tbody>
<tr>
<td><strong>Department:</strong></td>
<td>Clinical R&amp;D</td>
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## Title:
Double-blind, randomized, placebo controlled trial to study safety, local and systemic availability of TMC120 from a vaginal ring.

## Clinical Phase:
1

## Trial No:
IPM 008/ TMC120-C131

## Summary:
This Phase I trial will assess the feasibility of using a vaginal ring to deliver the candidate microbicide TMC120 for 7 days. The study population will consist of 13 healthy sexually abstinent women. Safety and tolerability will be assessed through clinical and laboratory assessments. Feasibility of drug delivery will be assessed by measuring TMC120 concentrations in vaginal fluids, vaginal and cervical epithelial tissue, and plasma.

## Trial Location:
Gent, Belgium

## Investigators:
- Dr. Luc Van Bortel, Drug Research Unit Gent, UZ Gent (principle investigator)
- Dr. Marleen Temmerman, Department of Gynecology, UZ Gent (sub-investigator)

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## Sponsor:
International Partnership for Microbicides (IPM), Silver Spring, Maryland, USA

## Co-Sponsor:
Tibotec Pharmaceuticals Ltd., Little Island, Co Cork; IRELAND

## Trial Coordinator:
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1010 Wayne Avenue, Suite 1450  
Silver Springs, Maryland, USA, 20910  
Tel.: (301) 608-2221 / fax: (301) 608-2241

## Treatment:
Seven-day exposure to a TMC120 vaginal ring in 10 subjects; seven-day exposure to a placebo vaginal ring in 3 subjects.
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<tr>
<th><strong>GCP Statement:</strong></th>
<th>This trial will be conducted in accordance with this protocol, Good Clinical Practices, and applicable regulatory requirements.</th>
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<tbody>
<tr>
<td><strong>Confidentiality Statement:</strong></td>
<td>The information in this document contains trade secrets and commercial information that are privileged or confidential and may not be disclosed unless such disclosure is required by law. In any event, persons to whom the information is disclosed must be informed that the information is privileged or confidential and may not be further disclosed by them. These restrictions apply to all future information supplied to you which is indicated as privileged or confidential.</td>
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