Pre-Study – Feasibility Questionnaire

<table>
<thead>
<tr>
<th>Study title:</th>
<th>Repetitive levosimendan infusions for patients with advanced chronic heart failure (LeoDOR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol (version, date):</td>
<td>1.0</td>
</tr>
<tr>
<td>EudraCT-No.:</td>
<td><em>will be applied</em></td>
</tr>
<tr>
<td>IMP:</td>
<td>Levosimendan (Simdax®)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Site No.:</th>
<th>e.g. AUT01</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI (name/address):</td>
<td>Title, name</td>
</tr>
<tr>
<td></td>
<td>Institution</td>
</tr>
<tr>
<td></td>
<td>Address, zipcode, city</td>
</tr>
<tr>
<td>Substitute (name/address):</td>
<td>Title, name</td>
</tr>
<tr>
<td></td>
<td>Institution</td>
</tr>
<tr>
<td></td>
<td>Address, zipcode, city</td>
</tr>
<tr>
<td>STUDY TEAM</td>
<td>YES</td>
</tr>
<tr>
<td>------------</td>
<td>-----</td>
</tr>
<tr>
<td>Principal investigator has more than two years of experience conducting studies.</td>
<td></td>
</tr>
<tr>
<td>Practical experience with Levosimendan?</td>
<td></td>
</tr>
<tr>
<td>Familiarity with ICH-GCP and national regulations on the performance of clinical trial on medicinal products?</td>
<td></td>
</tr>
<tr>
<td>How many studies did you perform as principal investigator (in general)?</td>
<td></td>
</tr>
</tbody>
</table>

**Team Members**

- Principal Investigator
- Investigator
- Investigator
- Investigator
- Pharmacist
- Designated person for the lab
- Study Coordinator
- Study Nurse
- Other:

**Contact details**

**Study coordinator/-nurse:**

- Name
- Institution
- Address, zipcode, city
- Phone, E-mail
CONFLICT OF INTEREST (COI)

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Existing conflict of interest?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 If YES, please explain the existing COI:

REGISTRATION

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the study site have to register/apply for conduct of this study to hospital management?</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Does the study site have to register this study in any other registers or other local databases?</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

2 If YES, please mention name of local database:
<table>
<thead>
<tr>
<th>STUDY DESIGN</th>
<th>YES</th>
<th>NO</th>
<th>3 If YES, please comment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have any questions on the scientific background and objectives?</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Do you have any questions on the process of study/specific examinations?</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Do you have any questions on the timelines (start, end and time of recruitment)?</td>
<td></td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please choose one of the below listed options. Please note that the treatment group you choose is obligatory for the whole study duration as the randomization will be done accordingly.</td>
</tr>
<tr>
<td>Treatment group: 6h-infusion every 2 weeks</td>
</tr>
<tr>
<td>Treatment group: 24h-infusion every 3 weeks</td>
</tr>
<tr>
<td>BOTH treatment groups</td>
</tr>
</tbody>
</table>
## ETHICS COMMITTEE

<table>
<thead>
<tr>
<th>EC name</th>
<th>Address, zipcode, city</th>
<th>Country</th>
<th><em>(Name and address of ethics committee)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td><em>(Name of ethics committee's chairman)</em></td>
<td>Is someone simultaneously member of the study team and the ethics committee?</td>
<td>YES</td>
</tr>
<tr>
<td>How often are ethics committee meetings conducted?</td>
<td>x per month</td>
<td>Date of next three meetings, starting with July/August 2017:</td>
<td>1. meeting:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. meeting:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. meeting:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4. meeting:</td>
</tr>
</tbody>
</table>

## PHARMACY

<p>| Is a pharmacy involved in the study and has the study medication to be send directly to the pharmacy? | YES | □ NO |
| Name and address of pharmacy: | Name and address of alternative institution: |
| Name | Name |
| Institution | Institution |
| Address, zipcode, city | Address, zipcode, city |
| <strong>Name of person responsible:</strong> | <strong>Name of person responsible:</strong> |
| Name | Name |
| Institution | Institution |
| Address, zipcode, city | Address, zipcode, city |
| Phone, E-mail | Phone, E-mail |</p>
<table>
<thead>
<tr>
<th>Are secured storage rooms/lockable cabinets available in order to provide access only by authorized site staff?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is a refrigerator providing adequate storage conditions (2-8°C, light protected) available?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Is the refrigerator providing enough space for study medication?</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AVAILABILITY OF PATIENTS</th>
<th>YES</th>
<th>NO</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have any restrictions or do think that any exclusion or inclusion criteria may influence recruitment?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Enough patients recruitable?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>How many new patients per month are treated at your site?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>How many patients do you feel you could realistically enroll in this study per year/quarter?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>How many patients fulfilled the inclusion criteria during the last year/quarter?</td>
<td>YES</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Please give an estimation on how many patients will possibly drop-out during the study:</td>
<td>YES</td>
<td>NO</td>
<td>(estimated percentage)</td>
</tr>
<tr>
<td>How many patients of the study site are participating in clinical studies?</td>
<td>YES</td>
<td>NO</td>
<td>(total number or estimated percentage)</td>
</tr>
</tbody>
</table>
## EVALUATION OF STUDY SITE

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the study site provide a freezer (-80°C)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the freezer (-80°C) at the study site hold enough space for the samples? You will need four 96-well racks per study patient.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the study site provide a centrifuge (1600g)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Space for monitoring is available. Where?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Language

Please indicate the language of documentation (e.g. worksheets, patient files) at your study site:

### Source data

**a) If source data is only available electronically:**

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access rights for monitor defined</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Security system (description available)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit trail implemented</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**b) If source data is available in paper form:**

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>Comment</th>
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<td>Are secured storage rooms/lockable cabinets available in order to provide access only by authorized site staff?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where is source data stored?</td>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

Do you want to take part in the LeoDOR trial including acceptance to all formal requirements including GCP, national laws, audits, archiving, etc.?

☐ YES

☐ NO

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(date) (signature PI) (name in block capital)