Cooperation within the framework of PPP

DEVELOPMENT OF THE FIELD OF BIO EQUIVALENCY STUDIES IN ARMENIA

Yerevan 2016
What we suggest?

- Complex establishment which will enable to conduct bioequivalence studies for generic drugs.

What we will have?

- Capacity to develop Drug Registration Documentation (Dossiers) for the generics registration in various countries.
Why it is important?

• Drug producer needs to get the evidence of compliance of generic drug to brand one. The only way to prove it is bioequivalence study results.

• Drugs registration bodies in all countries require Dossiers, as an evidence that this generic drug is equivalent to brand one. It is impossible to register generics without Dossiers.

• Bioequivalence study will assure that new generic is safe, efficient and corresponds to quality requirements.
What we have for the project implementation?

• Clinic for volunteers /for in vivo studies/
• Analytical laboratory /for blood sample analyses/
• R&D department /for project management, statistical analyses, report writing and Dossiers design/
Our input

- Laboratory (building, initial equipment, all technical infrastructures, computers, software, chemicals, laboratory consumables; trainings, staff, quality infrastructure)
- Clinic (building, initial furniture, all technical infrastructures)
- R&D (building, well trained staff)

Our contribution for project period (3 years)

- 2,995,000 USD
Additional funding input

- Laboratory (additional equipment, statistical software, computers, trainings)
- Clinic (additional furniture and equipment, staff, trainings, introduction of quality system)
- R&D (trainings)
- 1 pilot project implementation with final Dossier

Additional funding contribution for project period (3 years)

- 1.666.000 USD
### Proposed amount (for 3 years)

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Tonus/AMD</th>
<th>Additional funds/AMD</th>
<th>Project Total Cost /AMD</th>
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<tbody>
<tr>
<td>1</td>
<td>Renovation, new construction</td>
<td>919,000,000</td>
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<td>2</td>
<td>Hardware</td>
<td>2,800,000</td>
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<td>Software</td>
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<td>Staff salaries</td>
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<td>171,240,000</td>
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<td>Consultants’ fees (trainings, quality system implementation, audit, acknowledgement)</td>
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<td>Etc. (equipment, furniture, promotion)</td>
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<td>TOTAL USD</td>
<td>2,995,000</td>
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</table>
EXPECTED IMPACT

• Export opportunities for bioequivalence study services from Armenia.
• TNCs (Transnational Corporations) involvement into Armenian market.
• Increased production volume of the generics in Armenia.
  ✓ Extended portfolio of Armenian generics
  ✓ Increased export volume to the CIS and other countries
  ✓ Improved reputation of Armenian drugs
• Capacity of full analyses of generic drugs manufacturing from raw material to registration-ready condition.
• Whole Complex will be the platform for young specialists and University students to develop their professional skills and knowledge.