



«TONUS-LES» LTD

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)

N	Description	<i>Tonus/AMD</i>	<i>Additional funds/AMD</i>	<i>Project Total Cost /AMD</i>
1	Renovation, new construction	919,000,000	0	919,000,000
2	Hardware	2,800,000	5,500,000	8,300,000
3	Software	980,000	28,454,400	29,434,400
4	Staff salaries	43,200,000	171,240,000	214,440,000
5	Consultants' fees (trainings, quality system implementation, audit, acknowledgement)	0	40,125,000	40,125,000
6	Etc.(equipment, furniture, promotion)	476,320,000	557,211,680	1,033,531,680
	TOTAL USD	2,995,000	1,666,000	4,661,000

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.