

DEVELOPMENT OF BIO EQUIVALENCY STUDIES IN ARMENIA

- **Location: Yerevan, Armenia**
- **Project cost: 4,6 million USD**

PROJECT BACKGROUND:

The project is about the establishment of a complex which will enable to conduct bioequivalence studies for generic drugs.

- Drug producers need to get the evidence of compliance of generic drug to brand one. The only way to prove it is bioequivalence study results.
- Drug 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.

The project implementation will involve:

- 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/



THE IMPLEMENTING COMPANY OFFERS:

- 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)
- 2,971,200 USD investment for the project period of 3 years

REQUIRED CONTRIBUTION

- 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
- 1.653.600 USD investment for project period (3 years)

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PROPOSED AMOUNT (FOR 3 YEARS)

N	Description	Tonus/USD	Additional funds/USD	Project Total Cost/USD
1	Renovation, new construction	1,893,000	0	1,893,000
2	Hardware	5,800	11,300	17,100
3	Software	2,000	58,700	60,700
4	Staff salaries	89,000	352,900	441,900
5	Consultants' fees (trainings, quality system implementation, audit, acknowledgement)	0	82,700	82,700
6	Etc.(equipment, furniture, promotion)	981,400	1,148,000	2,129,400
TOTAL USD		2,971,200	1,653,600	4,624,800

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.
- Students will be able to develop their professional skills and knowledge.