

TC DOCUMENT

I. BASIC INFORMATION FOR TC

▪ Country/Region:	Uruguay
▪ TC Name:	Strengthening technical and human capacities for genomic services exports
▪ TC Number:	UR-T1119
▪ Team Leader/Members:	Mikael Larsson (INT/TIU), Team Leader; Pablo M. Garcia (CUR/TIU); Pablo Angelelli (CUR/CTI); Joonseob Kwon (INT/TIU); Guillermo Eschoyez (LEG/SGO); and Yasmin Esteves (INT/TIU).
▪ Indicate if: Operational Support, Client Support, or Research & Dissemination.	Research and Dissemination
▪ Reference to Request: (IDB docs #)	N/A
▪ Date of TC Abstract authorization:	July 2, 2014
▪ Beneficiary:	Institut Pasteur de Montevideo
▪ Executing Agency and contact name:	Institut Pasteur de Montevideo
▪ Donors Providing Funds	Knowledge Partnership Korea Fund for Technology and Innovation (KPK)
▪ IDB Funding Requested:	US\$590,000
▪ Local counterpart funding, if any:	US\$379,900
▪ Execution period:	30 months
▪ Disbursement period:	34 months
▪ Required start date:	September 1, 2014
▪ Types of consultants (firm or individual consultants):	Individuals
▪ Prepared by Unit:	Trade and Investment Unit (INT/TIU)
▪ Unit of Disbursement Responsibility:	Uruguay Country Office (CUR)
▪ Included in Country Strategy (y/n); ▪ TC included in CPD (y/n):	Yes
▪ GCI-9 Sector Priority:	Competitive Regional and Global Integration

II. OBJECTIVES AND JUSTIFICATION OF THE TC

- 2.1. The general objective of the project is to develop local capacity in Uruguay for the analysis of human genomic sequences, both in research and support for genomic medicine and scientific development of new products and technologies. As a result, new spin off companies and service laboratories will be created with a clear focus on exporting genomic services, which in turn will generate a positive socioeconomic impact and augment the country's international competitiveness in

the global services sector. The specific objectives of the current project are: (i) strengthening the technical capacities of researchers working on human genomics in Uruguay through the development of a comprehensive training program in South Korea and Uruguay; (ii) producing scientific and technical advances in the sequencing and analysis of human genomes in Uruguay; (iii) promoting the creation of new companies and service laboratories with export profiles in the field of human genomics; (iv) stimulating the Latin American integration in the field of human genomics by facilitating the exchange of human resources in the region; and (v) disseminating the advances in the field of human genomics to the scientific and academic communities in the country that are related to the pharmaceutical and life sciences sectors.

- 2.2. Technology and scientific Research and Development (R&D) are transforming traditional healthcare services, allowing disruptive innovations to better suit medical and preventive treatments to patients, thus improving people's lifestyles and health. One such advancement is occurring in the area of Genomic Medicine (GM), a specific segment of what is known today as the field of Personalized Medicine (PM), which involves the sequencing of a human genome and the use of that information to prevent, diagnose and treat complex diseases. Among some of the derived benefits of this type of customized medicine, there are many testing methods that can be directly improved through the application of sequencing technology, such as diagnostics, early diagnostics, prognostics (predicting the possible diseases based on hereditary characteristics), and pharmacogenomics tests (taking into consideration the patient's genotype to optimize drug treatment), just to name a few.
- 2.3. The latest worldwide advances in sequencing capabilities are rapidly generating a scenario where genomic medicine will play an increasingly important role in human health. At the same time, the growing knowledge about the human genome variability can interpret in a new way evolutionary processes leading to the distribution of differences between human populations. The current automated procedures lead to obtain genomic sequences, reducing somewhat more routinely tasks (either of "wet-lab" and bioinformatics). Thus, it is becoming increasingly important to interpret intelligently the data generated as well as to maximize the benefit of having a growing number of genomes available. In this sense, it becomes strategically important to develop such capabilities nationally, which will be required at both fundamental and applied research, in diagnosis, as well as in the development of new biotechnology products. Given the enormous potential arising from the development of the field, this project aims at establishing a group of researchers in Uruguay with the ability to analyze human genome data generated from the new sequencing technologies, as well as to create the foundations of a highly specialized exports servicing sector.
- 2.4. While being a relatively new trend that has gained momentum only recently, the international market for PM is expected to reach US\$452 billion by 2015, whereas the genetic testing global market is at US\$730 million. In this context, the development of technology and scientific research has allowed to reduce costs

at an incredible amount. A decade ago, the cost of sequencing a full human genome used to be close to US\$300 million and nowadays it is estimated to cost US\$3,000, and expected to cost less than US\$1,000 in the near future. In this sense, the improvement of technology availability and R&D in developing countries as well as the advantages of outsourcing and offshoring initiatives in this field will allow costs to be reduced significantly more, giving more people the opportunity to benefit from it. Uruguay, an example of a developing country searching for growing opportunities arising in this field, is currently actively promoting the development of its offshoring capabilities,¹ in which the pharmaceutical and life sciences sector constitutes one of the four main pillars in the promotion of global services. With a pool of skilled physicians and scientists, as well as institutions that are already providing these services, Uruguay has many opportunities in this field of study and business. One of the most recognized institutions that is already on this path and has substantial potentialities in the country is the Institut Pasteur de Montevideo (IP Montevideo), a non-profit organization that aims at contributing to prevent and treat illnesses through education, research and collaboration with healthcare public policies.² In an effort to consolidate Bioinformatic and Genomic technologies capabilities, the IP Montevideo has decided to put those areas in its strategic development plan for the next decade. In order to achieve the objective of this strategy, the IP Montevideo is dedicating a significant portion of the Uruguay-Innova II EU Funds to consolidate the Bioinformatics area by hiring two new Senior Scientist positions, as well as acquiring new Sequencing equipment (IlluminaMiSeq) for the institute. In addition, through a Mercosur Regional Project (FOCEM Project COF 03-11) a new area, which expanded the surface of the original building in about 1,300 sq mts, has been built. This new space area is now hosting the renewed Bioinformatics Lab (which expanded to twice its original size) and a Business Bioincubator (BIOESPINN³, with operational costs funded by the Research and Development National Agency – ANII). The two main focus areas of the BIOESPINN business incubator are Genomics and Bioinformatics. In fact, more than half of the projects approved to begin incubation during 2014, are related to PM and Genomics. Complementarily, IP Montevideo team leaders of the Bioinformatics Lab and the Molecular Biology Unit, are focusing their efforts on strengthening the institute's human capacities related to the fields of Genomics and Bioinformatics. All of these efforts currently undertaken by the institute,

¹ In 2012, the IDB approved a US\$10M loan to support the development of export global services in Uruguay (UR-L1060).

² The current proposed project involves other key institutions and actors from Uruguay and the LAC region. Particularly, the Department of Biological Anthropology of the Universidad de la Republica (UdelaR), as well as other groups from the UdelaR such as the Organization and Genome Evolution Lab, and Bio-mathematics Section of the Sciences Faculty. Other institutes such as CLAEH and the ORT University will also be involved in the project either through the involvement of its researchers or by providing professors to dictate some of the courses contemplated in Phase I of the Project.

³ Bioespinn is a newly created incubator located at the IP Montevideo, which provides state of the art equipment, access to technological platforms, business support and finance to biotechnology, bioscience, biopharmaceutical, med-tech and healthcare start-ups, spin-outs and SMEs

- together with the specific activities planned under the proposed TC, intend to generate the necessary basic conditions for the proliferation of a new sector of genomic export services in Uruguay.
- 2.5. As immediate precedents to the project, in 2006 IP Montevideo created two Technological Platforms aimed at developing technologies, providing services and training personnel in the areas of experimental genomics and in bioinformatic analysis (Molecular Biology Unit and Bioinformatics Unit). Since then, these two Units have achieved important advances, including the development of several conjunct projects in agro-genomics (massive sequencing of rice, cereals, micro-organisms such as bacteria, yeasts and parasites). However, further advancements in human genomics that will ultimately impact the field of PM, would need further strengthening of both the technological and human capacities of the institute.
 - 2.6. In recognition that international cooperation with recognized academic leaders is paramount to the development of the field, IP Montevideo has established a key partnership with the Seoul National University (SNU, South Korea), through its Genomic Medicine Institute. SNU, ranked 35th in the QS World University Rankings 2013, and 6th in the Top 10 Universities in Asia for Natural Sciences⁴, is at the forefront of research in human genomics, semiconductors, automobiles, information technology (IT), and biotechnology. Furthermore, the specific experience of the Genomic Medicine Institute in education and post-doctoral training will assure excellence in capacity building and scientific exchange both in experimental genomics and bioinformatics. The Cooperation Agreement⁵ that has been signed between both organizations establishes the compromise to work together towards the consecution of the present project and builds the ground for a sustainable partnership beyond said work between the collaborating institutions.
 - 2.7. The objective and activities of this operation correspond to the Banks' Sector Strategy to Support Competitive Global and Regional Integration, as it will enhance trade and investment in the global/regional integration context between Uruguay and South Korea through: knowledge sharing, patent exploitation and human capacity enhancement in the area of Personalized Medicine.

III. DESCRIPTION OF ACTIVITIES/COMPONENTS AND BUDGET

- 3.1. The project will have two main components: (i) the strengthening of human capacities, and; (ii) the sequencing and analysis of human genomes in Uruguay.
- 3.2. **Component I: Strengthening Human Capacities in Uruguay for genomic services exports.** The goal of this component is the formation of a group of researchers, whose training will end in a specialization in human genomics, and whom will form the core group of a new multidisciplinary laboratory on human genome based at IP Montevideo in Uruguay. This group of highly qualified

⁴ <http://www.topuniversities.com/university-rankings/world-university-rankings/2013>

⁵ Said cooperation agreement was signed in July 2014. (See MOU).

technologists will be composed by graduate students (preferably PhDs) and recent postdocs with extensive expertise in genomics, bioinformatics, human genetics, population, quantitative, biological anthropology, biostatistics or other disciplines related to human genomics. The definitions of the profiles of interest shall be made by an Advisory Committee (AC) that will be created specifically for the project. In a first stage, each member of the core group will have an individual training plan comprised by general courses to be taken in Uruguay, so as to allow a leveling base that will ensure the success of a second stage, in which the researchers will participate in a set of specific tailored-made courses on the latest advances in human genomics and personalized medicine in South Korea⁶. It is expected that this core group will in turn train at least 50 other students and technologists from Uruguay in the areas of bioinformatics, genomics and personalized medicine, as well as 15 researchers from the Latin American region. It is also expected that, as a direct result of this component, and in collaboration with IP Montevideo's business incubator –BIOESPINN–, two start-up SME's will be created in Uruguay in the field of human genomics. Specifically, this component will finance: (i) training expenditures related to the academic and technical courses to be taken by researchers in South Korea and Uruguay; (ii) logistics expenditures related to the organization of an international course on human genomics in Uruguay; (iii) four individual consultancies with statistics, anthropology, medical and TI backgrounds.

3.3. **Component II: Sequencing of Human Genomes for genomic services exports.**

The goal of this component is to produce scientific and technical advancements in the sequencing and analysis of 80 human genomes, which will generate genome information able to unveil ancestral origins of both Amerindian and African ancestry in Uruguay⁷, as well as to generate a series of scientific results in personalized medicine and lung cancer genomics and treatment that will be groundbreaking for the development of the field in the country.⁸ This component will be divided in 3 different stages; (i) Ancestry Sequencing Program (8 months): In this first stage, there will be a characterization at the genomic level of key individuals with (admixed) Amerindian and African ancestry in Uruguay. The relative lack of historical registers and scarcity of ethnical information deserves special interest for both subgroups. In this stage, a number of 20 genomes will be

⁶ Previous to the beginning of any training activities in South Korea, IP Montevideo – through SNU – will inform and obtain the corresponding non objection from the authorities of said country.

⁷ The IP Montevideo team has already submitted for consideration and approval by the Ethics Committee of the Sindicato Medico del Uruguay (SMU) the [protocol](#) that will be used for obtaining informed consent by donors. No sequencing activities within the project will start until said approval is received from the SMU. Additionally, starting in September 2014, all research projects that involve human populations will be studied by the IP Montevideo's Ethics Committee currently under conformation.

⁸ In light of the history of political activism that has surrounded human population genetics research in Uruguay, under the scope of this project, IP Montevideo is working in coordination with the Department of Biological Anthropology of the UdelaR in developing a strategy to mitigate said risk. As a first step, once the SMU's Ethics Committee approves the protocol to obtain informed consent by donors, a series of meetings with key reference groups will be organized in order to inform them of the scope of the project, as well as to discuss their potential involvement in the project.

sequenced and the bioinformatics analysis will be performed at the IP Montevideo; (ii) General Uruguayan Population Sequencing (12 months). During this second stage, the pilot-sequencing program will be extended to 30 more genomes using the validated protocols from the first stage, but now with the aim of covering the genomic variability of the whole country; (iii) Genome Sequencing Medical Interest (12 months): In this third and final stage, a comprehensive program for medical genomics will be established, starting with the sequencing of 30 additional genomes, targeting cases with medical interest and high impact in Uruguay. These genomes will be solved with a much higher coverage in order to include low frequency variants. All of the bioinformatics analysis will be done in its entirety at the IP Montevideo, establishing key capacities to analyze human genomes and leading to the development of a services sector that will be able to export these capacities and know-how to other countries. Specifically, this component will finance: (i) expenditures related to genomic sequencing services; (ii) sample processing inputs expenditures; (iii) the acquisition and installation of storage and data processing equipment, and: (iv) logistics expenditures related to the organization of events to disseminate the knowledge acquired through the development of the project.

Indicative Results Matrix:

Indicators	Unit	Baseline		Year 1 (2014)		Year 2 (2015)		Year 3 (2016)		Expected Completion Date
		Value	Year	Planned	Actual	Planned	Actual	Planned	Actual	
Component I: Strengthening Human Capacities in Uruguay										
Researchers of the core group recruited	#	0	2013	5		5		-	-	06/30/2015
International researchers recruited by the project	#	0	2013	2		1		-	-	05/31/2015
Training courses finalized by the core group of researchers	#	0	2013	2		3		-	-	06/30/2016
Training stays finalized by the core group of researchers	#	0	2013	1		4		-		06/30/2016
Regional participants attending international course on human genomics	#	0	2013	-		15		-		7/31/2015
Students and professionals from the pharma and life sciences sectors attending a dissemination seminar	#	0	2013	-		-		50		11/30/2016
New SME start-ups created	#	0	2013	-		1		1		11/30/2016
Component II: Sequencing of Human Genomes										
Sequenced genomes analyzed - Ancestry	#	0	2013	10		10		-		03/31/2015
Sequenced genomes analyzed – General Uruguayan Population	#	0	2013	-		20		10		07/31/2016
Sequenced genomes analyzed – Medical Interest	#	0	2013	-		-		30		06/30/2016
Patents filed as a result of the project	#	0	2013	-		-		1		11/30/2016

Indicative Budget (USD)

Activity/ Component	Description	Bank	Counterpart Funding (IP Montevideo – in-kind)	Total
Component I	Training Activities - in Korea	36,000.00	38,415.00	74,415.00
	Training Activities - in Uruguay	54,900.00	58,585.00	113,485.00
	Support Consultants for Sequencing & Analysis	48,000.00	34,900.00	82,900.00
	International Training for Young Researchers from the Region	16,000.00	30,000.00	46,000.00
Component II	Genome Sequencing Services ⁹	171,500.00	160,000.00	331,500.00
	Sample Processing	35,000.00	25,900.00	60,900.00
	Dissemination Activity	17,100.00	32,100.00	49,200.00
	Equipment	175,000.00		175,000.00
External Audit		10,000.00		10,000.00
Coordination, Administration and Monitoring		26,500.00		26,500.00
TOTAL		590,000.00	379,900.00	969,900.00

IV. EXECUTING AGENCY AND EXECUTION STRUCTURE

- 4.1 This operation will be executed by the Institut Pasteur de Montevideo. IP Montevideo has an extensive experience in executing international cooperation projects. As an example, IP Montevideo has successfully executed a grant of EU Funds for Eur 3,1M (Uruguay Innova I), and is beginning the execution of the second stage (Uruguay Innova II, Eur 1 M). Another relevant grant is in execution now, is a Mercosur's Convergence Regional Project (FOCEM Project that includes partners from Paraguay, Brazil, Argentina and Uruguay) to strengthen research and human resources in experimental biomedicine fields. Uruguayan budget for this project is of USD 1,6 M. Also, IP Montevideo executes an average of 100 different small and medium size research projects a year, funded by the Research and Development National Agency – ANII and other international agencies (ICGEB, RIIP, PTR). In addition the Institute has a specific operational Unit to carry out the management and coordination of the Project (Scientific Management Unit), regarded as excellent by the Funding Agencies such as ANII. The contracting of project consultants and services will be carried out by the IP Montevideo according to the Bank's policies for the Selection and Procurement of Consulting Services Financed by the Bank.
- 4.2 The Executing Agency will generate and provide to the Bank semiannual technical and financial reports detailing the advancement of the project and a work plan for the following semester. Reports will be delivered within thirty (30) days of the finalization of each semester. Additionally, an external audit covering

⁹ Contracted and supervised by SNU

the entirety of the project will be generated and provided to the Bank within 30 days of the finalization of the disbursement period.

V. MAJOR ISSUES

- 5.1 The success of the project will depend on a significant level of engagement and participation of the partners. The operation will mitigate the risk by engaging high level authorities from each organization in the supervision of the project. The project will also be a key successful case for government officials to promote in an intensive promotion strategy. In such case, the project has already obtained approval and support from the Uruguayan Ministry on Education and Culture and from the Directorate for Science and Technology in Uruguay.
- 5.2 Another risk is the reduced number of specialists in genomics and bioinformatics in Uruguay, although to some extent there are human resources and expertise in the area of human population genetics. To mitigate the scarcity of possible highly trained students and postdocs in the area of bioinformatics, IP Montevideo will attract a diverse pool of talents from the region and it will seek an aggressive policy of attracting returning scientists which are currently part of the Uruguayan Diaspora living abroad.

VI. EXCEPTIONS TO BANK POLICY

- 6.1 There are no exceptions to Bank policy.

VII. ENVIRONMENTAL AND SOCIAL CLASSIFICATION

- 7.1 This operation does not present environmental and social risks. It was classified as Category “C” in the [Environmental and Screening Classification](#).

Required Annexes:

Annex I:	Request Letter
Annex II:	Terms of Reference
Annex III:	Procurement Plan

**STRENGTHENING TECHNICAL AND HUMAN CAPACITIES FOR GENOMIC SERVICES
EXPORTS**

UR-T1119

CERTIFICATION

I hereby certify that this operation was approved for financing under the Knowledge Partnership Korean Fund for Technology and Innovation (KPK) through a communication dated July 3, 2014 and signed by Mr. Suyeong Yu, Director of the International Bureau, Ministry of Strategy and Finance of the Republic of Korea. Also, I certify that resources from said fund are available for up to US\$590,000 in order to finance the activities described and budgeted in this document. This certification reserves resources for the referenced project for a period of four (4) calendar months counted from the date of eligibility from the funding source. If the project is not approved by the IDB within that period, the reserve of resources will be cancelled, except in the case a new certification is granted. The commitment and disbursement of these resources shall be made only by the Bank in US dollars. The same currency shall be used to stipulate the remuneration and payments to consultants, except in the case of local consultants working in their own borrowing member country who shall have their remuneration defined and paid in the currency of such country. No resources of the Fund shall be made available to cover amounts greater than the amount certified herein above for the implementation of this operation. Amounts greater than the certified amount, may arise from commitments on contracts denominated in a currency other than the Fund currency, resulting in currency exchange rate differences, for which the Fund is not at risk.

ORIGINAL SIGNED

8/22/2014

Sonia M. Rivera
Chief
Grants and Co-financing Management Unit
ORP/GCM

Date

APPROVAL

Approved: ORIGINAL SIGNED

AUG 25 2014

Antoni Estevadeordal
Sector Manager
Integration and Trade Sector
INT/TIU

Date