BIOBANKING DURING WAR: EXPERIENCE OF AUDUBON BIOSCIENCE

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About Audubon Bioscience

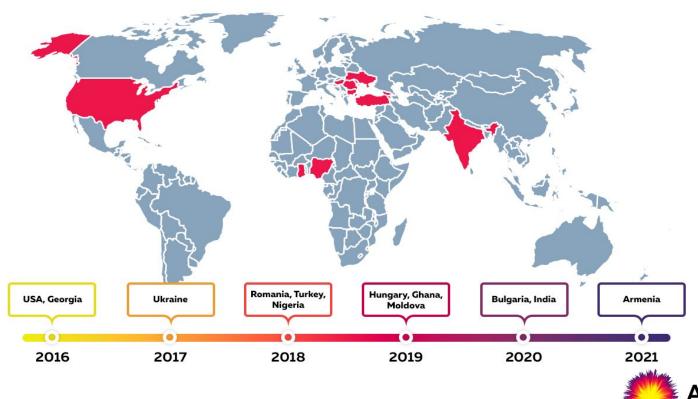
- **Audubon Bioscience** is an innovative provider of high quality biospecimens and associated clinical information (biobank and contract research organization).
- Focus primarily on **prospective**, **investigator driven**, **collections** to provide the most customized sample and data cohorts.
- All biospecimens are collected with the donor's informed consent (ICF) or an approved Waiver of consent (WOC) with oversight of an Institutional Review Board (IRB) or Ethics Committee **(EC)** approval.
- Founded in New Orleans, LA June, 2016 with current headquarters in Houston, TX, however > 30% employees (including CEO) are Ukrainians.

Audubon Bioscience Mission:

To provide biospecimen solutions to researchers from various medical fields to support the discovery of new life-saving diagnostics and treatments.



Our Global Presence



Research Biobanking Legal Framework



МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ

вул. М.Группевського, 7, м. Київ. 01601, тел. (044) 253-61-94, E-mail: moz/@moz.gov.us. web: http://www.moz.gov.ua, код €ДРПОУ 00012925

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ва № 36 від 26.04.2023 р

Товариство з обмеженою відповідальністю «Аудубон Біосаєнс»

Міністерство охорони здоров'я України розглянуло лист товариства з обмеженою відповідальністю «Аудубон Біосаєнс» від 26 квітня 2023 року № 36 щодо надання роз'яснення регуляції діяльності організацій, що мають у своєму складі дослідницькі біобанки, та повідомляє про наступне

Відповідно до частини першої статті 2 Закону України «Про ліцензування видів господарської діяльності» (далі – Закон), цей Закон регулює суспільні відносини у сфері ліцензування видів господарської діяльності, визначає виключний перелік видів господарської діяльності, що підлягають ліцензуванню, встановлює уніфікований порядок їх ліцензування, нагляд і контроль у сфері лішензування, відповідальність за порушення законодавства у сфері ліцензування видів господарської діяльності. Згідно пункту 16 частини першої статті 7 Закону, ліцензуванню підлягає діяльність банків пуповинної крові, інших тканин і клітин людини згідно з переліком, затвердженим Міністерством охорони здоров'я України. Ліцензійні умови провадження господарської діяльності банків пуповинної крові, інших тканин і клітин людини згідно з переліком, затвердженим Міністерством охорони здоров'я, визначено постановою Кабінету Міністрів України від 02 березня 2016 р. № 286. Перелік тканин і клітин людини, з якими дозволена діяльність банків пуповинної крові, інших тканин і клітин людини, затверджений наказом Міністерства охорони здоров'я України від 20 квітня 2012 року № 276, зареєстрованим в Міністерстві юстиції України 05 липня 2012 р. за № 1124/21436 (далі - Перелік тканин і клітин). До Передіку тканин і клітин надежать: пуповинна (кордова) кров та виділені з неї клітини, пуповина (пуповинний канатик) та виділені з неї клітини, плацента та виділені з неї клітини, гемопоетичні стовбурові клітини, виділені з периферичної крові, сполучна тканина та виділені з неї клітини, тканина яєчника/яєчка, матеріал ембріофетального походження та виділені з нього клітини, молочні зуби та виділені з них клітини, очне яблуко або його складові.

Перелік платних послуг, які надаються в державних і комунальних закладах охорони здоров'я та вищих медичних навчальних закладах, затверджений постановою Кабінету Міністрів України від 17 вересня 1996 р. № 1138 (далі - Перелік платних послуг). Відповідно до пункту 43 розділу І Переліку платних послуг, послугами, що надаються згідно з функціональними повноваженнями державними і комунальними закладами охорони здоров'я є збір та обробка біологічних зразків осіб, які надали на це згоду, а також супровідної знеособленої клінічної інформації та передача їх для третіх осіб для проведення



за, _{29/116762-23 від 03:05 2023} юзділу X Порядку проведення пнаказом Міністерства охорони

Ukrainian Association of Research Biobanks (2021)



Section I (43), Resolution of the Cabinet of Ministers of Ukraine, #1138, Sep 17, 1996, (the "List of Paid Services")



Chapter X (11), Procedure for Conducting Pathological Autopsy, Ministry of Health of Ukraine, # 1877, Sep 06, 2021



Section 14, Procedure for Transportation of Human Anatomical Materials ..., Import ... and Their Export ..., Resolution of the Cabinet of Ministers of Ukraine, #720, Aug 5, 2020



Laws on the Transplantation and Licensing umbilical cord blood, other human tissues and cells banks do not apply to research biobanking (research biobanks)

Our Ukrainian Team

7 months earlier Celebrated 5-year anniversary of company with a retreat in Kyiv



Audubon's Team at 5th Anniversary Celebration

Kyiv, Ukraine - July 5th, 2021 - This summer Audubon Bioscience celebrates its 5th anniversary. It all started in the summer of 2016 in the Audubon area (hence the name of the company) of New Orleans, LA, where our CEO, Dr. Rostyslav Semikov, started his postdoctoral research fellowship at the Louisiana State University (LSU) Neuroscience Center. He and Cabirac's family (two other cofounders) started the company by providing biosamples procurement services to various US clients from clinics in Eastern Europe. Since then the company has grown to almost 100 employees globally and partner's sites in 12 countries in the US, Europe, and Africa.



Last weekend our Eastern European team got together for a celebration of this first, but significant milestone in our company's history. We gathered to teambuild, listen to experts in various fields, discuss, analyse and DREAM about the future! It was a great time together! These two days, especially in the post-COVID world, presented a great opportunity for everyone to finally meet in person and enjoy each other's presence and company. It was a great time together!

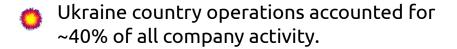


Our Ukrainian Team



Around February 2022

- Made up of ~40 team members
- ~20 employees from our corporate office lived in Kviv
- Clinical partnerships/collaborations with ~35 Ukrainian clinics + hospitals
- Was actively working on 37 projects











Preliminary Planning Phase (PPP)

- Awareness of the seriousness of a potential interruption to our global team
- Company wide e-mail on February 1, 2022 from CEO and HR Director
- Top management came together to construct a Business Contingency Plan (BCP)

Business Contingency Plan (BCP)

- BCP presented on February 14, 2022 to discuss and finalize immediately
- Human Resources + Operations + Revenue divisions worked fluidly as a team to come up with options on how to smoothly transfer people, projects, specimens and data.

What will trigger activation of our plan?

- Signs of escalation
- Official request from <u>Ukrainian</u> authorities to evacuate from Kyiv



Proposed Options for Employees

In the event of military escalation:

A. Evacuation of Ukraine-based colleagues and their families to <u>Turkey</u>

B. B. Evacuation of Ukraine-based colleagues and their families to <u>Western Ukraine</u>

C. Organization of work & life while staying in Kyiv



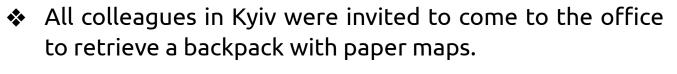
Limitations

All our plan of actions can be limited because of the following acts:

- Roads closed
- Airports closed
- Mobile/internet connection cut off
- Bank payments stopped
- Inability to buy fuel/food/medication etc.
- False news and propaganda influence
- Riots/strikes/looting etc.



Preparedness

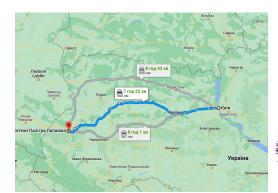


Backpacks sent to colleagues who live in other regions.

Colleagues are instructed on how to keep constant communication with top management

Cottage home rented in Western Ukraine a few days

before the war





February 24, 2022

- A large-scale army invasion severely interrupts our Ukrainian operations
- Our team faces many challenges (both the local Ukrainian team and our global team)
- We preliminarily planned for and anticipated a disruption in the weeks ahead

Human Resources Plan

Revenue Plan Operations Plan



Communication is Key

Our Operations team came together with the HR and Revenue teams to organize real time evacuation of our staff with documents, laptops, and ambient specimens to the Western Region of Ukraine. Colleagues advised to keep ALL working files on shared Google Drive.



Detailed company emails to internal employees on status of the company, safety of local team members and how to contact clients regarding re-allocation with specific updates and possible delays to their projects



Shared Google sheets between Top Management and local Ukrainian employees on exact location (address, phone #, persons traveling with, status, plans)



Multiple Slack channels created for company-wide and group specific communication on real time events



Telephone/cell service widely used where internet was unavailable



Human Resources Plan Execution

- After 2-3 days into war □ instructed our colleagues to go to Western Ukraine
- Constant communication to those who were actively traveling/evacuating and offering support to them
- Coordinating temporary hotel accommodations, stipend of \$100/day, financial assistance with all travel costs to evacuate
- Communicating temporary salary reductions for 3-6 months for top management/leaders
- Notifying consultants and part-time employees of temporary lay offs
- Additional home rented in Western Ukraine once missile attacks occurred

Business/Revenue Plan Execution

- Moved active projects to other country sites (Turkey, USA, Armenia, Bulgaria, Romania) and immediately informed those clients of their project changes, accruals affected, supplies or kits affected.
- Immediate economical reductions within the company.
- Salary reduction on leaders, stopped new business development, no new hires, freeze of research department & no conferences or travel not already planned.
- Focused on essential operations only and got a mid-term loan to finance our own costs.

Operations (Specimen/Data) Plan Execution

- Prospective and banked collections stored mostly in office in Kyiv in -80C freezers with stable electric supply/generators (even for blackouts during planned power outages)
- Freezers were equipped with external alarms and temperature loggers and were left behind with frozen samples.
- FFPE blocks put into boxes and evacuated with employees to Western Ukraine in first few days after war starting.
- Data/paper records packed into lidded, prelabeled boxes and evacuated with employees to Western Ukraine
- Database for local sample records stored on company shared Google Drive and all records were scanned in advance into Google Drive in the event of a loss.











Operations (Specimen/Data) Plan

- Agreements with a local transport company put in place incase of a large-scale transfer of equipment and samples needed
- In April/May 2022, gained access to office to get prospective cases transferred by refrigerated transport truck to Romania and further shipped to clients
- In June 2022, transfer of FFPE blocks initiated by car to Romania and delivery to New Orleans, LA for permanent storage
- New Orleans Team matched up of every FFPE block ID against data spreadsheet and put into order in USA



Social Impact through



- Audubon founder and many colleagues made a volunteer team to help Ukraine: Peace and Development Foundation (501c3)
- In 1 year donated, raised and delivered over \$300,000 in aid
- Donations and logistics for Ukraine winter humanitarian aid: 1. Generators, 2. Woodburn Stoves, 3. Sheepskin Boots







APRIL 5, 2022

In Wake of Russian Invasion, Ukrainian Founder of Audubon Bioscience Appeals to PMC's Network for Additional Funds to Support Nonprofit Peace and Development Foundation

Writing from his perspective as the Ukrainian founder and CEO of Audubon Bioscience. biobank with offices in 12 countries. Rostysla Semikov, M.D., has shared a letter encouraging PMC's members and supporters to donate to the Peace and Development Foundation, a nonprofit institution founded in 2016 to promote peace, education, and innovation in Ukraine. Donations to the foundation will go toward providing medical supplies, humanitarian aid, transportation, and shelter for refugees fleeing Ukraine in the wake of Russia's ongoing invasion.



"Audubon Bioscience has funded the first five years of charitable activities, but now the needs have become much greater." Semikov's letter reads. "We ask you to help us save the lives of Ukrainian people by donating and engaging in our

You can view Semikov's letter on the back page of this reprint. Use the following link to donate: http://www.peacedevelopment.fund/.

Social Impact through



- December 2022: Vanderbilt University Medical Center in Nashville, TN hosts Ukrainian transplant physicians for observership with the help of Senator Bill Frist, MD.
- January 2023: LSU Emergency Medicine offers to donate hyperbaric chamber, equipment and CO2 monitors & volunteer their technicians to train Ukrainian physicians on how to use equipment for trauma in war
- February April 2023: American Association for Cancer Research (AACR) and American Society of Clinical Oncology (ASCO) agree to support efforts in bringing best practices to Ukraine



Social Impact through



April 2023 Annual Meeting in Orlando: collaborated with AACR to negotiate medical internships for Ukrainian physicians with US leading cancer centers





QUESTIONS, COMMENTS?



Thank you for your time!

