Creating an Artificial Intelligence Market for Health service

Boris Zingerman
INVITRO - Head of eHealth Department
NBMZ - General Director

The Association of Developers and Users of Artificial Intelligence Systems in Medicine
The Association of Developers and Users of Artificial Intelligence Systems in Medicine (National Base of Medical Knowledge). The goals of the Association are to bring together market participants and support the developments of MDSS market and artificial intelligence systems for healthcare.

- To accelerate the introduction of advanced Artificial Intelligence Market Development for Healthcare
- Consolidation in the Russian developments, access to international markets
- Ensuring equal access to validated biomedical data for Russian developers of Medical Decision Support systems (MDSS)
- Improving the efficiency of healthcare, reducing mortality, morbidity and medical errors, implementation of new innovative health care technologies
- Establishing an accessible, variable, and extensive expert environment for the development and practical application of digital technology in the healthcare system.

https://nbmz.ru/
Largest network

1,397
Total number of service centers worldwide

31,500
Patients per day

124,000
Tests per day

* Data as of July 17, 2018

- 1260 patient service centers (PSC) from Kaliningrad to Yuzhno-Sakhalinsk in Russia*
- 57 patient service centers in Ukraine*
- 33 patient service centers in Belarus*
- 44 patient service centers in Kazakhstan*
- 2 patient service centers in Armenia*
- 1 patient service center in Kyrgyzstan*

Total number of service centers worldwide: 1,500

Patients per day: 124,000

Tests per day: 31,500

* Data as of July 17, 2018
Our laboratories

**laboratories in Russia:**
- Moscow
- Saint Petersburg
- Chelyabinsk
- Novosibirsk
- Samara

**laboratory in Ukraine:**
- Dnepropetrovsk

**laboratory in Belarus:**
- Minsk

**laboratories in Kazakhstan:**
- Almaty
- Astana
Our team

We are proud of our team of professionals that includes scientists, physicians, technologists, research and laboratory assistants, etc. All the staff members are trained and certified in applicable areas. Today INVITRO has more than 11,000 employees, and 1,500 of them are doctors.
3D Bioprinting Solutions is a Laboratory for Biotechnological Research founded by INVITRO, the largest private medical company in Russia. The laboratory develops and produces bioprinters and materials for 3D bioprinting, and also develops innovative technologies in the field of biofabrication.

On December 3, 2018, the Organ.Aut bioprinter was delivered to the ISS on board the Soyuz MS-11 manned spacecraft. For the first time on orbit, cosmonaut-researcher Oleg Kononenko printed human cartilage tissue and a rodent thyroid gland using a bioprinter.
Robot Fedor and bioprinter met in space!

Which technologies will appear on Earth earlier?
<table>
<thead>
<tr>
<th>No.</th>
<th>Application</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Drug Discovery and Research</td>
<td>Разработка и исследование лекарств.</td>
</tr>
<tr>
<td>2.</td>
<td>Medical Imaging and Diagnostics</td>
<td>Медицинские изображения и диагностика.</td>
</tr>
<tr>
<td>4.</td>
<td>Predictive Insight and Risk Analytics</td>
<td>Прогнозная аналитика и анализ рисков.</td>
</tr>
<tr>
<td>5.</td>
<td>Lifestyle Management and Monitoring</td>
<td>Управление и мониторинг образа жизни</td>
</tr>
<tr>
<td>6.</td>
<td>Wearables/Sensor Data Insight</td>
<td>Обработка и анализ информации с носимых устройств.</td>
</tr>
<tr>
<td>7.</td>
<td>Chronic Condition Management</td>
<td>Менеджмент хронических состояний.</td>
</tr>
<tr>
<td>8.</td>
<td>Virtual Assistance</td>
<td>Виртуальные ассистенты.</td>
</tr>
<tr>
<td>9.</td>
<td>Mental Health</td>
<td>Психическое здоровье.</td>
</tr>
<tr>
<td>10.</td>
<td>Emergency Room and Surgery</td>
<td>Неотложная помощь и хирургия.</td>
</tr>
</tbody>
</table>
Gartner Hype Cycle

- **AI**
- **TELEMEDICINE**

- **Expectations**
  - Peak of Inflated Expectations
  - Slope of Enlightenment
  - Plateau of Productivity

- **Innovation Trigger**
- **Trough of Disillusionment**

**Time**
Telemedicine as a Platform for Artificial Intelligence

Wearables/Sensor

Communications

prescription

Integration Platform

Monitoring
Medical Messenger as a convenient way of remote communication of the patient with his doctor

Medsenger provides:

• Competitive advantage - attracting new customers and retaining old ones.

• Increasing customer loyalty, their commitment to treatment and satisfaction with medical services.

• Additional income without increasing loads.
Medsenger.AI provides a platform for connecting intelligent agents (IAs) to the «patient-doctor» dialogue

IA should be created by many external developers and solve small highly specialized tasks.
A specific IA agent is connected to the channel if its task is relevant for a given patient and, if necessary, this IA is adjusted by a doctor.

Examples:
• Monitoring pressure and medication.
• Control of the compatibility (affordability) of drugs.
• Patient diaries (on the example of monitoring cancer patients).
• Providing personalized informational materials.
Medsenger can be integrated with telemonitoring devices of any kind. In particular, with almost any cardiомonitors, blood pressure monitors, blood glucose meters.
SaMD
Трудности перевода

Статья: Емелин И.В., Зингерман Б.В., Лебедев Г.С.

Проблемы определения ключевых терминов медицинской информатики

Информационно-измерительные и управляющие системы, No.12, 2009г., с 15-23.

ГОСТ Р ИСО/ТС 20514-2009 «Информатизация здоровья. Электронный учет здоровья. Определения область применения и контекст» (ISO/TR 20514:2005 Health informatics — Electronic health record — Definition, scope and context)

ГОСТ Р ИСО/ТС 18308-2008 «Информатизация здоровья. Требования к архитектуре электронного учета здоровья» (ISO 18308:2011 Health informatics — Requirements for an electronic health record architecture)

EMR — электронная медицинская карта (ЭМК)
EHR — интегрированная электронная медицинская карта (ИЭМК)
PHR — персональная электронная медицинская карта (ПМК)
Lost in Translation

IMDRF/SaMD WG/N10FINAL:2013 / Software as a Medical Device (SaMD): Key Definitions

IMDRF/SaMD WG/N12FINAL:2014 / Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations

IMDRF/SaMD WG/N23 FINAL:2015 / Software as a Medical Device (SaMD): Application of Quality Management System

IMDRF/SaMD WG/N41FINAL:2017 / Software as a Medical Device (SaMD): Clinical Evaluation

SaMD – Software as a Medical Device

dословный перевод - literal translation

Программное обеспечение как медицинское изделие

In Russian, “Device” is an object of the material world.

Предпочитительное определение - Preferred definition

Медицинское программное обеспечение (health software)
Информатизация здоровья

КЛАССИФИКАЦИЯ УГРОЗ БЕЗОПАСНОСТИ
ОТ МЕДИЦИНСКОГО ПРОГРАММНОГО
ОБЕСПЕЧЕНИЯ

Health informatics — Classification of safety risks from health software

Издание официальное

Москва
Стандартинформ
2010
Senator Krugly proposed to exclude medical software from the category of medical devices

СЕНATOR КРУГЛЫЙ ПРЕДЛОЖИЛ ИСКЛЮЧИТЬ МЕДИЦИНСКОЕ ПО ИЗ КАТЕГОРИИ МЕДИЗДЕЛИЙ
### 1. SaMD Categories

<table>
<thead>
<tr>
<th>State of Healthcare situation or condition</th>
<th>Significance of information provided by SaMD to healthcare decision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treat or diagnose</td>
</tr>
<tr>
<td>Critical</td>
<td>IV</td>
</tr>
<tr>
<td>Serious</td>
<td>III</td>
</tr>
<tr>
<td>Non-serious</td>
<td>II</td>
</tr>
</tbody>
</table>

**Table № 1 – Матрица классов риска ПМИ, принятая IMDRF**

<table>
<thead>
<tr>
<th>Клиническая ситуация</th>
<th>Цель (назначение) использования предоставляемой ПМИ информации</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Диагностика или лечение (ДЛ)</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Критическая (КС)</td>
<td>3, IV.i</td>
</tr>
<tr>
<td>Серьезная (СС)</td>
<td>2b, III.i</td>
</tr>
<tr>
<td>Ординарная (НС)</td>
<td>2a, II.i</td>
</tr>
</tbody>
</table>
### ISO/TS 25238:2007

**Health informatics — Classification of safety risks from health software**

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Catastrophic</th>
<th>Major</th>
<th>Considerable</th>
<th>Significant</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very high</td>
<td>A</td>
<td>A</td>
<td>B</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>High</td>
<td>A</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>C</td>
</tr>
<tr>
<td>Medium</td>
<td>B</td>
<td>B</td>
<td>C</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Low</td>
<td>B</td>
<td>C</td>
<td>D</td>
<td>D</td>
<td>E</td>
</tr>
<tr>
<td>Very low</td>
<td>C</td>
<td>C</td>
<td>D</td>
<td>E</td>
<td>E</td>
</tr>
</tbody>
</table>
Botkin.AI solution
Screening (revision) of diagnostic images

Task:
• automatic revision of diagnostic images, in which radiologists did not detect malignant tumors

Target:
• Increased detection of oncology, especially in the early stages

Healthcare providers
Depersonalized medical images are downloaded from Central Archive of Medical Images

Radiologists
Expert radiologists verify the signs of malignant neoplasms

Artificial Intelligence
Images are analyzed using the Botkin.AI platform

Outcome
Additional cases with malignant neoplasms detected
Перевод терминов и их адаптация к российским реалиям / Translation of terms and their adaptation to Russian realities

<table>
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<th>Clinical Evaluation</th>
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<tbody>
<tr>
<td><strong>Valid Clinical Association</strong></td>
</tr>
<tr>
<td>Is there a valid clinical association between your SaMD output and your SaMD’s targeted clinical condition?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Analytical Validation</th>
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<tbody>
<tr>
<td>Does your SaMD correctly process input data to generate accurate, reliable, and precise output data?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does use of your SaMD’s accurate, reliable, and precise output data achieve your intended purpose in your target population in the context of clinical care?</td>
</tr>
</tbody>
</table>

*Figure 4- Clinical Evaluation Process*
Есть ли клиническая корреляция выходных данных вашего МПО на основе выбранных входных данных и алгоритмах с обстоятельствами его использования?

Примеры существующих доказательств:
• поиск в литературе;
• оригинальные клинические исследования;
• клинические рекомендации.

Примеры создания новых доказательств:
• анализ вторичных данных;
• выполнение клинических испытаний.
Thank you for your attention!