

ФАРМАЦЕВТИЧНИЙ ФОРУМ

«КЛІНІЧНІ ВИПРОБУВАННЯ В УКРАЇНІ. ЄВРОПЕЙСЬКА ІНТЕГРАЦІЯ»

Pharmaceutical forum

CLINICAL TRIALS IN UKRAINE. EUROPEAN INTEGRATION

Клінічні дослідження в Україні сьогодні та в майбутньому

Today & Future of Clinical Trials in Ukraine

Iryna Magdik

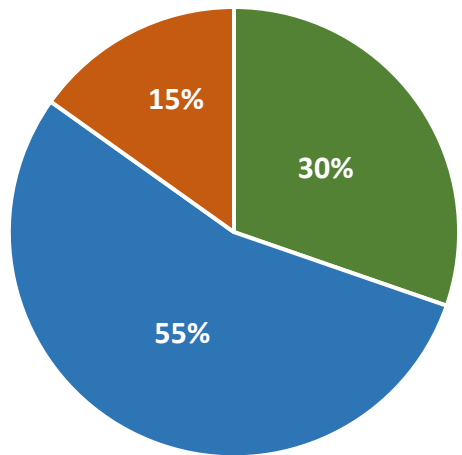
Clinical Trials Subcommittee
European Business Association

Kyiv, Ukraine
29.06.2023

Clinical Trials Subcommittee European Business Association

EBA CTS Members

>30 companies -
International and
Local Pharma, CROs,
CT Logistic, CT sites

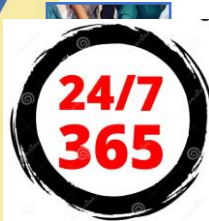


■ CRO ■ Pharm RO ■ Logistic

February 24, 2022...

Hold on and adapt!

CT support during martial law - focus of CT Subcommittee



Communication with companies on problematic issues

- Weekly and unscheduled meetings of the Board and CTS
- Regular surveys from May 2022
- Round tables – CTS + external participants + SEC + MoH
- WG to solve concrete problem



Subjects' safety. Data retention

- Transfer and support
- Monitoring and consultations



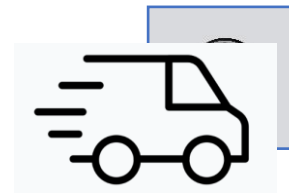
Safety & work of personnel

- Support
- Relocation
- Remote work opportunities
- Remote monitoring



CT sites & LEC

- Work in the conditions of **martial law**
- Relocation of centers
- Remote coordination
- Remote work of LEC
- The principle of "One opinion"
- Financial issues, application of eSignature



CT supplies, Logistics – IMP etc.

- CT materials stocks
- Use of available transport, pharmacy premises for IMP
- Export of biosamples
- DTP Practice
- Moving between CT sites



Adaptation of the conditions for CT submission for expertise to the MoH & SEC

- Submission in electronic form
- Electronic communication and document management
- Financial questions



Communication with the MoH, SEC, Verkhovna Rada, DSLZU, etc. on regulatory issues

- Joint work on SEC recommendations
- Adaptation of the conditions for submitting CT materials for expertise
- Legislative initiatives
- Amendments to bylaws

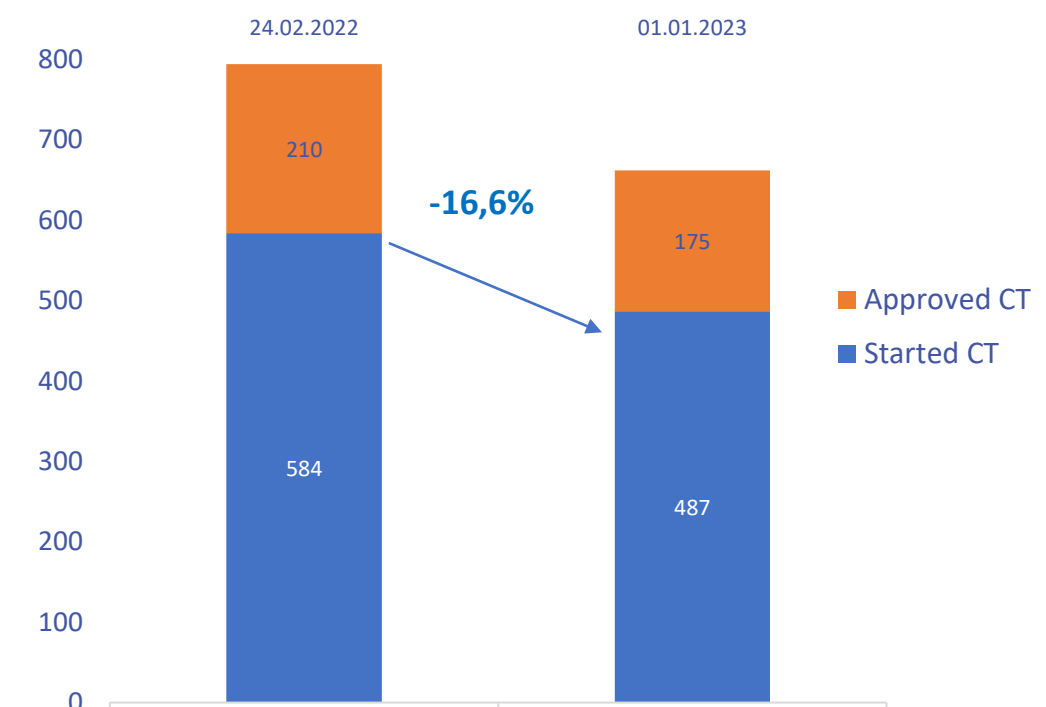
In 2022 industry adapted fast to ensure continuity: < 17% of active CTs were cancelled!

CT stakeholders adapted, adjusted processes ensuring the quality of CTs and protecting the rights, safety and well-being of the CT subjects

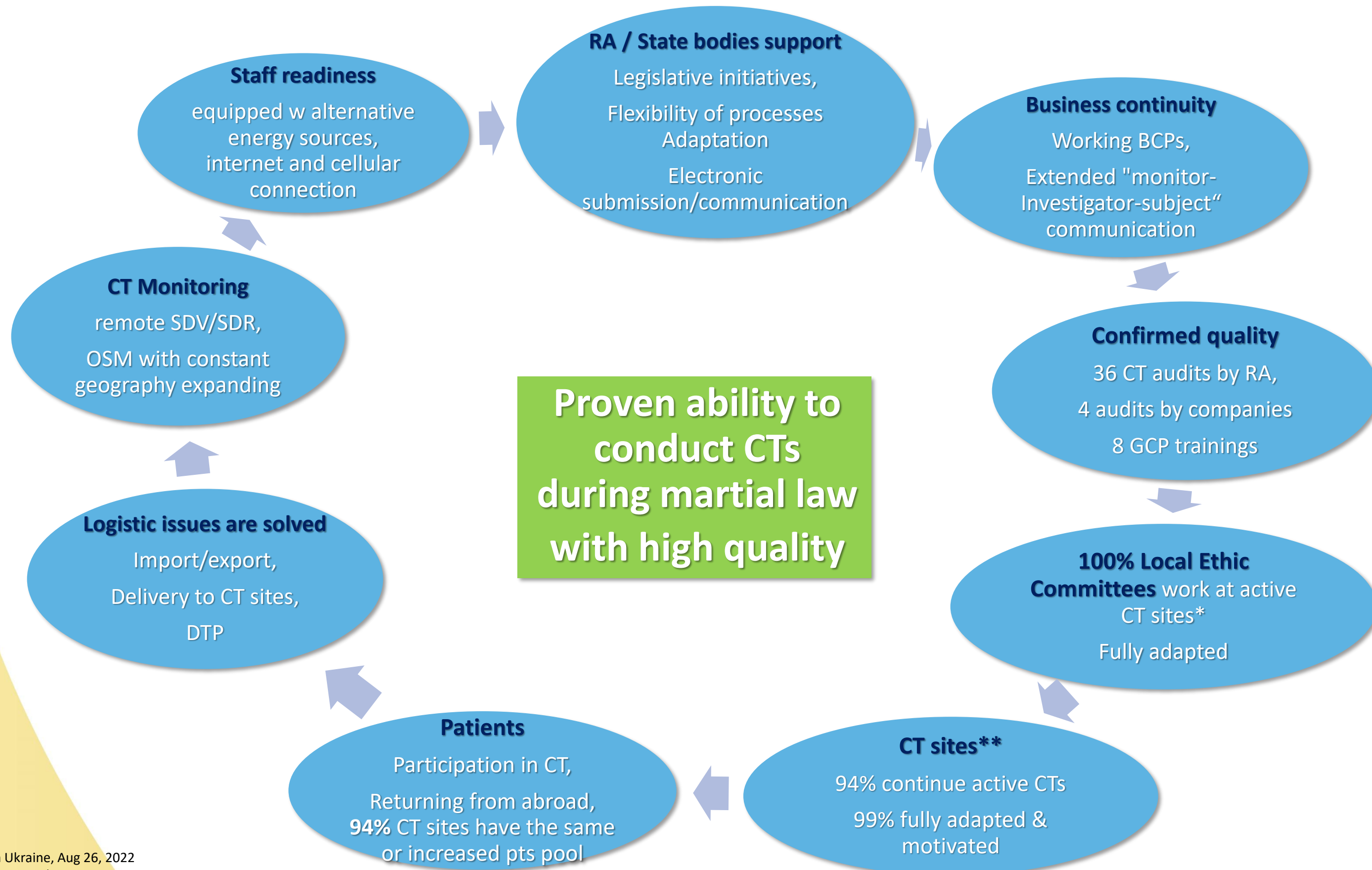
- ✓ **Business Continuity Plan**
- ✓ **24/7 communication / coordination / support:**
 - "monitor-Investigator-subject" - focus on patient safety and data integrity
 - "all CT stakeholders" – problem solving / remote work / regulatory support
- ✓ **Relocation support (Ukraine / abroad):**
 - CT sites
 - transfer of CT subjects
 - company personnel
- ✓ **Logistical issues solving:**
 - CT supply and delivery to UA, to local depot, sites, direct to patients
 - Bio-samples exportation; involving local labs

From Feb 24'2022 sponsors paused recruitment of new patients and start of new CTs

Actual CTs in Ukraine, 2022-2023



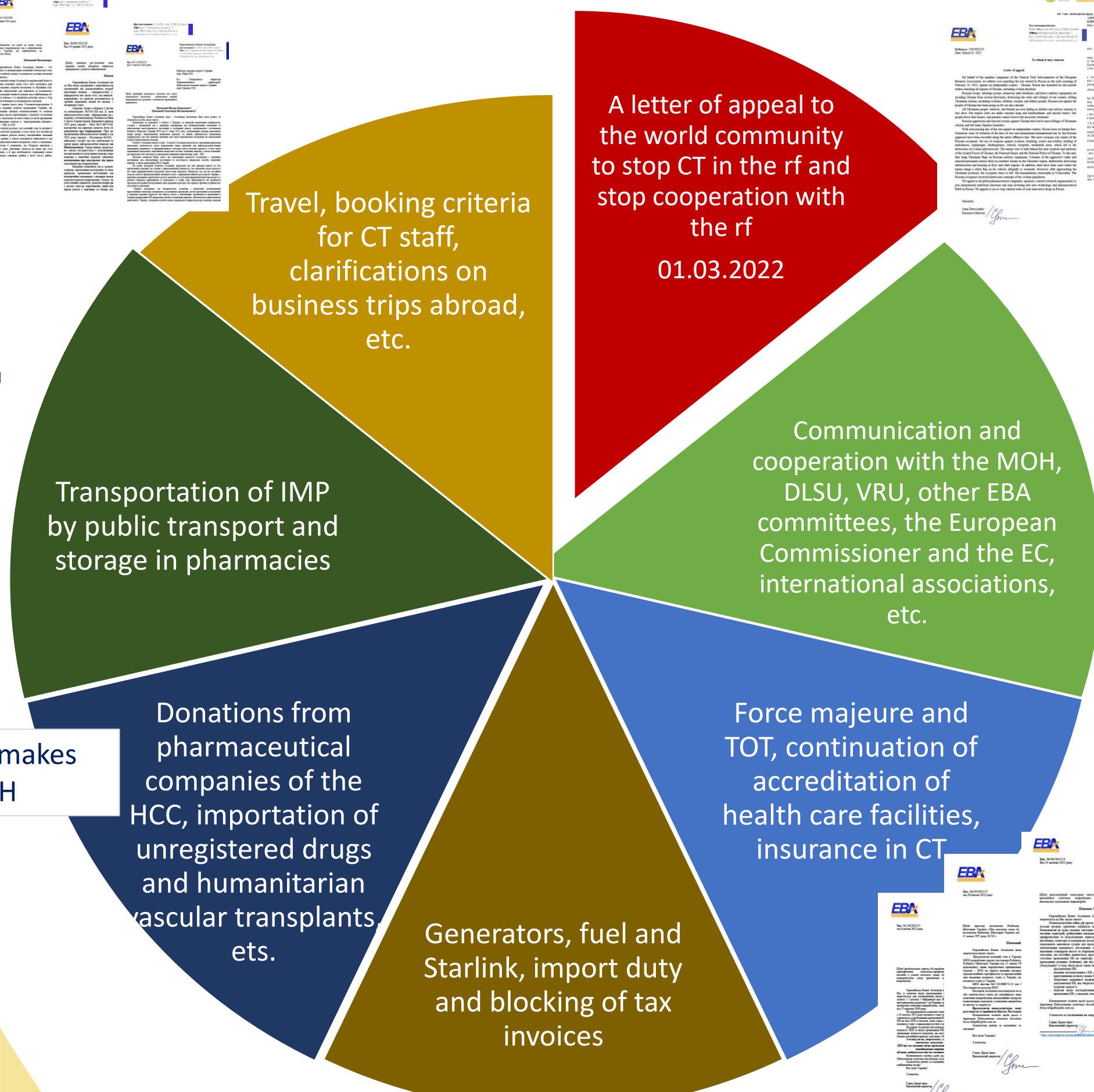
UA CT infrastructure proved ability to adapt & work effectively in extreme conditions: >80% of active CTs maintained and ran successfully



* EBA CTS Survey Status of CTs in Ukraine, Aug 26, 2022
** EBA CTS Survey Status of CT Sites in Ukraine, May 31, 2023

CTS Projects dictated by the war

258.9 million US \$, what makes > 9 billion 864 million UAH



A letter of appeal to the world community to stop CT in the rf and stop cooperation with the rf
01.03.2022

Travel, booking criteria for CT staff, clarifications on business trips abroad, etc.

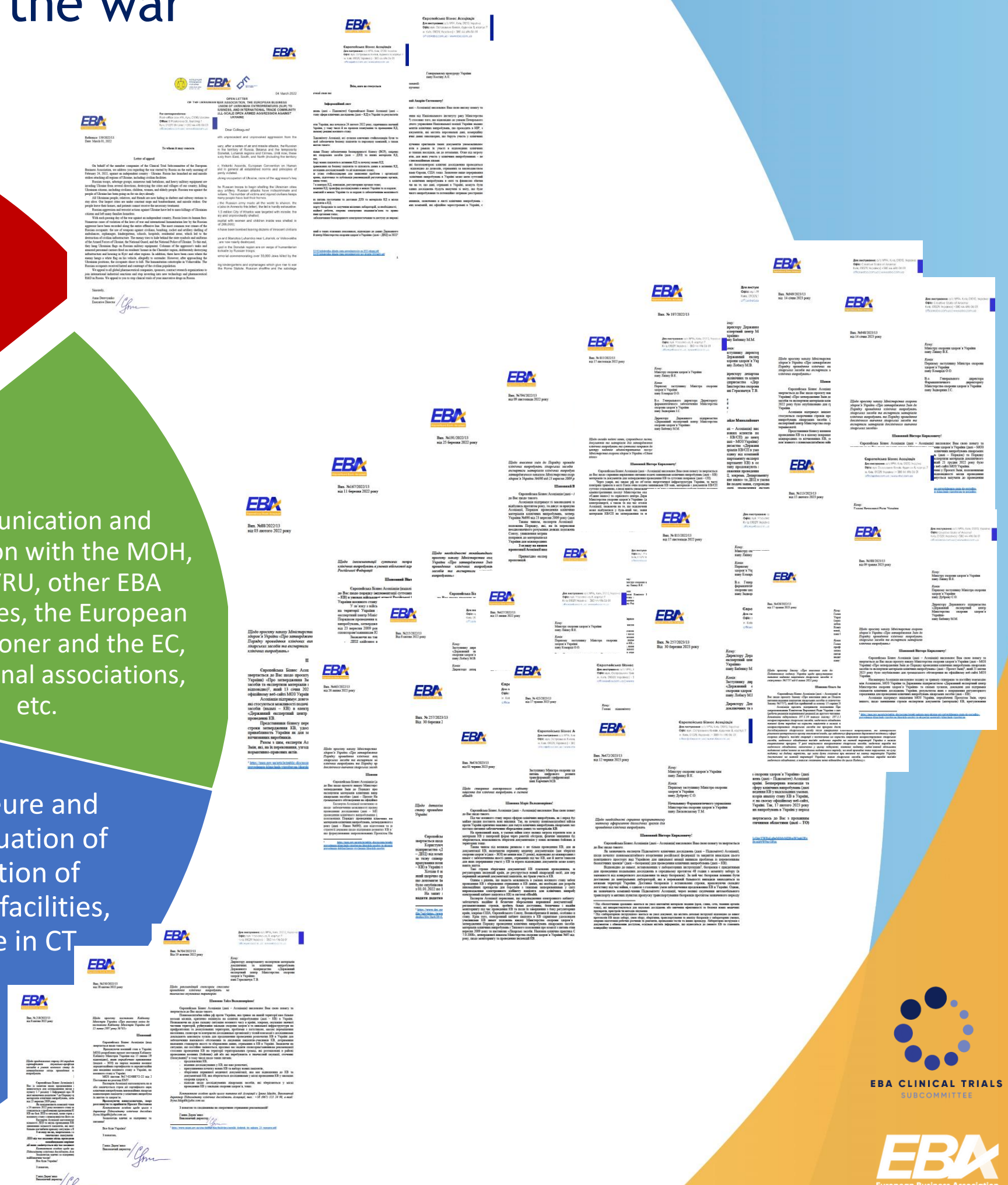
Communication and cooperation with the MOH, DLSU, VRU, other EBA committees, the European Commissioner and the EC, international associations, etc.

Force majeure and TOT, continuation of accreditation of health care facilities, insurance in CT

Generators, fuel and Starlink, import duty and blocking of tax invoices

Transportation of IMP by public transport and storage in pharmacies

Donations from pharmaceutical companies of the HCC, importation of unregistered drugs and humanitarian vascular transplants etc.



CTS key projects on CTs in 2022-2023

Legislation amended for CT – as result of “Business-VRU-MOH-SEC” cooperation



Digitalization of CTs (eSubmission, eIC, etc) and shortening of CT approval terms

- ✓ [MOH Order №2609 25.11.2021](#)
- ✓ [MOH Order №538 28.03.2022](#),
- ✓ [MOH Order №190 31.01.2023](#)

Harmonization of safety reporting in CT, labelling , etc. with EU requirements

- Amendment proposals to MOH Order 690 – under MOH consideration



CT approval terms, insurance, patients' protection, PTTA, etc.:

- ✓ [New edition of Law of Ukraine ‘On Medicines’ 2469-IX adopted 28.07.2022](#)

Modern regulatory requirements for CTs in Ukraine

- [Draft Law 5815](#) (amendment to CCU) registered in VRU
- Amendment to Law of Ukraine ‘On Medicines’, Project Law ‘On CTs’ – under CTS preparation



PTTA and CUP (CTS WG from 27.10.20 --> VRU 06.07.2021)

- ✓ [Law of Ukraine 5736 adopted 15.02.2022](#)
- ✓ [MOH Order №1525 24.08.2022](#)
 - [Draft Law 5737](#) (VAT/tax reduction) – adopted in the first reading



Regulation of CTs of MD and MD in the CTs of medicines

- Draft Law ‘On Medical Devices’ – proposals to VRU committee
- Draft Law ‘On CTs’



Awareness of CTs in Ukraine and abroad:

- ✓ Cooperation with the VRU, KMU, MOH, DEC, public organizations, associations of Ukraine and the EU
- ✓ Information project [‘Trials Truth’](#) with the support of MOH, SEC

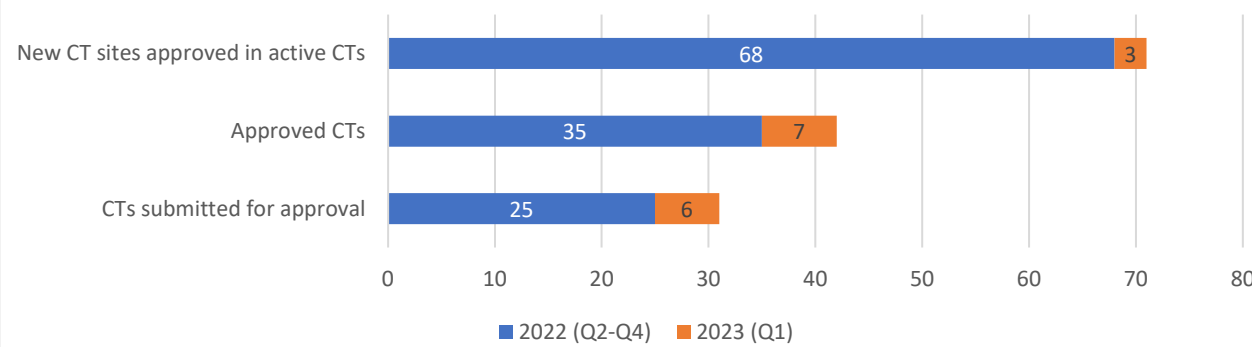


Going forward in 2023 – even stronger the CT industry, ready for new acceleration!

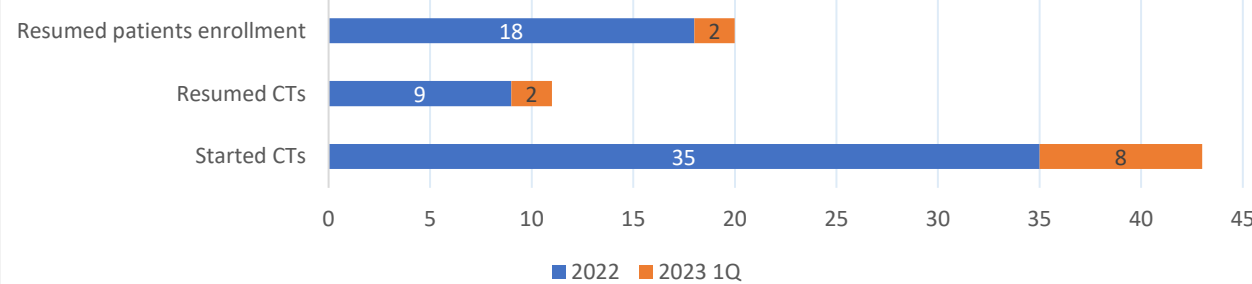
Recovery trends in 2022-2023



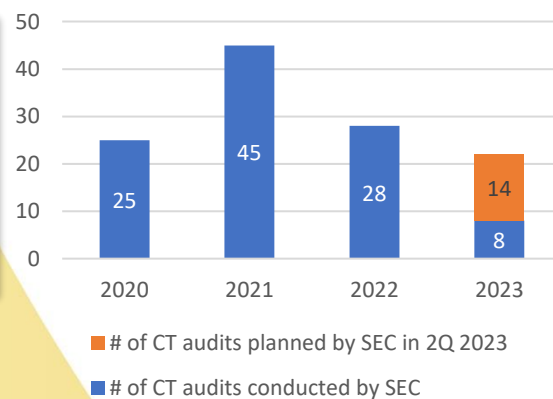
of submitted, approved, CTs and approved CT sites, period Q2 2022 - Q1 2023



of started new CTs, resumed CTs or CTs, where patients enrollment resumed, 2Q 2022-1Q 2023



CT Audits conducted by UA RA



- ✓ **SPONSORS' AUDITS:** 4 conducted (2 onsite), 9 planned (4 onsite)
- ✓ **8 GCP trainings / 411 participants**

- ✓ **32 patients returned to UA CT sites from abroad***
- ✓ **96% of active CT sites are fully adapted****
- ✓ **64% CT sites have active feasibilities**
- ✓ **37% CT sites have active CTs in start-up**

* Up to 30.04.2023
** CTS Survey of CT sites, May'23

Novelties to expect in 2023-2024?



Even SHORTER than 35 days TERMS OF CT APPROVAL!

Further DIGITALIZATION in CTs

Electronic medical documents in eHealth system, eICF, eISF

Final HARMONIZATION with EU REGULATIONS in alignment w Regulation 536/2014, shaping labelling requirements

TAX REDUCTION

on importation of medicines for PTTA/CUP programs

NEW APPROACHES IN CT

DCT, telemedicine, CT electronic documents, etc.

BIOSAMPLES FAST TRACK at customs

REGULATION OF MEDICAL DEVICES CT

Ukraine is ready to contribute to development of innovative treatment!

The time is now to ensure future success!

✓ Readiness of the CT sites 93-100%
with high interest & motivation



- **96%** of assessed Ukrainian clinical sites confirmed their **full adaptation and readiness**,
- **100%** - high interest and motivation,

- **64%** have **active feasibilities**
- **37%** CTs in **start-up**

EBA CTS: Survey on the Clinical Trial sites status in Ukraine, May 2023;
226 respondents took part in the survey



Clinical Trials dynamic & growing sphere before February 24, 2022

UKRAINE IS AN IMPORTANT PLAYER ON GLOBAL CT MARKET

1,2% Biopharma CT Mkt share

1,6% of Global pts

~ 60% for 5 TA:

Oncology (23%), Neurology & Psychiatry (16%), Gastroenterology (13%), Rheumatology (8%)

Presence of key R&D Pharm companies & CROs

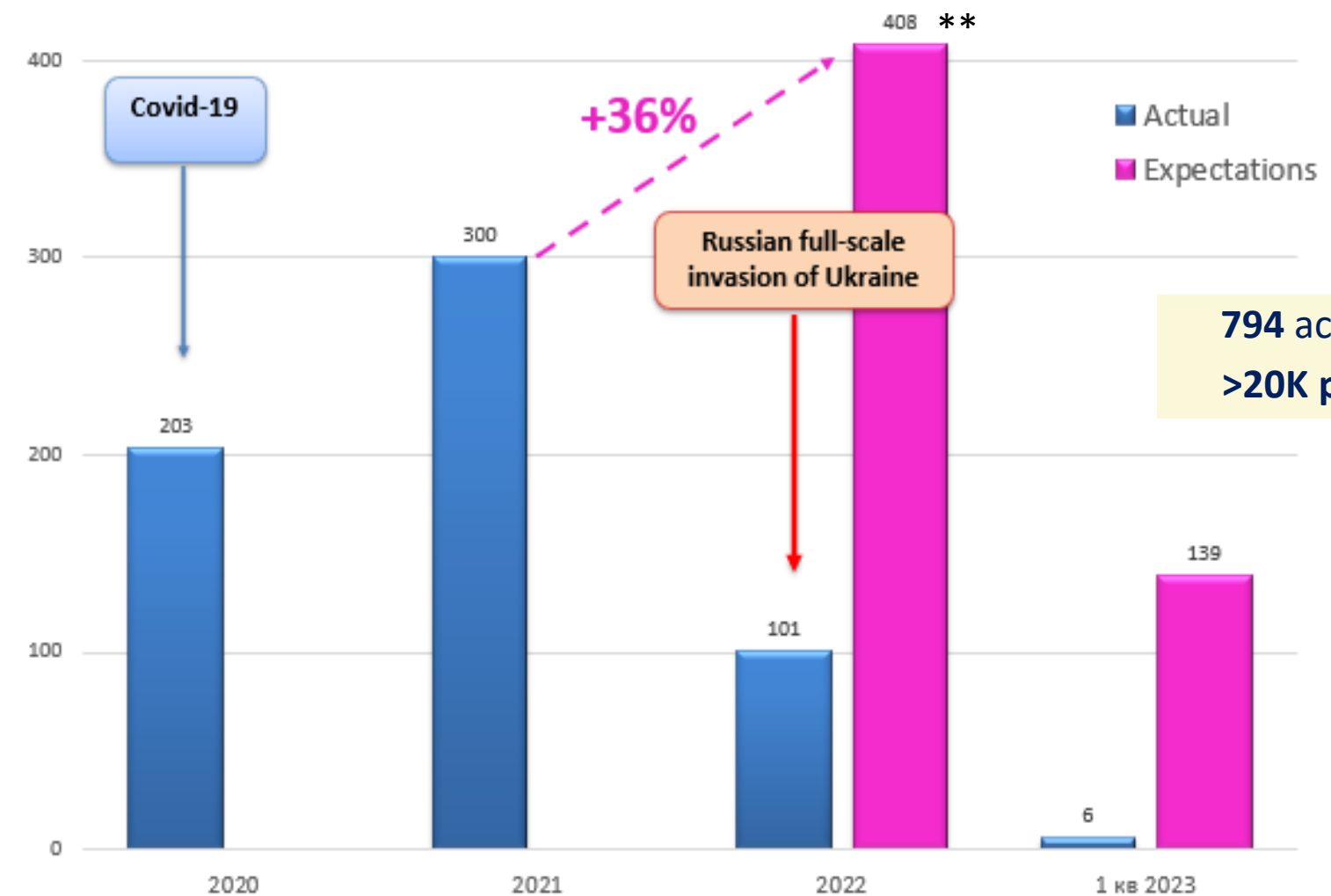
UKRAINE in EUROPE

Candidate to EU membership since 23 Jun 2022

#1 by area (fully located in Europe) - 603,7 km²

#6 by population - 41.4 million (60% urban)

30% ANNUAL GROWTH BEFORE THE WAR*



794 active CTs
>20K patients

Approval of international CT in Ukraine 2020–2023

~5% Phase I
~27% Phase II
~69% Phase III-IV

Today Ukraine's potential for CTs is used for 15%: big opportunity for growth in favorable environment

ADVANTAGES of UKRAINE for CT:

Developed CT infrastructure, skilled staff, big pull of patients, cost-effectiveness

- ✓ **HIGH-RECRUITING SITES**
- ✓ **EXPERIENCED HEALTHCARE PROFESSIONALS**
 - **1174** investigators (2019), ICH-GCP standards compliant
- ✓ **HIGH QUALITY OF CTs:**
 - 348 UA RA Inspections (2015-2022)
 - 12 FDA/EMA/PMDA inspections
- ✓ **CENTRALIZED HEALTH CARE SYSTEM** supports best recruitment
- ✓ **LARGE PATIENT POPULATION**, including naïve, e.g.:
 - ~1,2 mln onco patients (2021), 2^d in the cancer spread rate in Europe with ~140K new onco cases a year
- ✓ **WELL DEVELOPED INFRASTRUCTURE**
- ✓ **COST-EFFECTIVENESS**, even during martial law

Real potential
per year

>3000

Global CTs

>200K patients

Favorable regulatory environment

- ✓ **CLEAR AND SIMPLE APPROVAL PROCESS & START-UP:**
 - Submissions to CA, LEC & Contract execution - in parallel
 - No Central Ethics Committee, Local ECs – 1 per site
 - No Import/Export Licenses for CTs
 - IP custom clearance: 1-3 days
 - 7% VAT for IP import
- ✓ **RA SUPPORT**
- ✓ **FAST HC SYSTEM REFORM**
- ✓ **FINAL HARMONIZATION STAGE OF UA CT LEGISLATION WITH EU**
- ✓ **FAST EU INTEGRATION**

Vision for further cooperation and support from the EU & international partners

RECONSIDER CRITERIA to PLACE CTs in UKRAINE NOW

for specific regions, indications, etc.

Restore oversight of UA sites by external Competent Authorities – by EMA, FDA, MHRA, PMDA, others, including remote option

Facilitating of rapid implementation of new approaches in CTs - EU support for development of local requirements using international experience.

Establish baseline criteria for CTs resumption in UA jointly by EMA, MOH, and local business community through working group

Support for Central Labs establishment in UA, collaboration of Central Labs with country Labs in UA

Partnership with UA MOH for funding of eModule for CTs in eHealth system for it`s fast implementation.

Support of clinical sites & investigators for their further development - collaboration within international working groups



EBA CLINICAL TRIALS
SUBCOMMITTEE

EBA
European Business Association

Now it's time for the Global CT Players to make decisions based on the new reality

Ukrainian CT infrastructure has proven its ability to adapt quickly and work effectively in extreme conditions, maintaining the high quality of CTs

Ukraine has created the most favorable conditions for the rapid recovery of CTs

Unique UA experience is not an issue, but our strength on the global CT market.

Ukraine - country of choice for CTs in the coming decades



EBA CLINICAL TRIALS
SUBCOMMITTEE

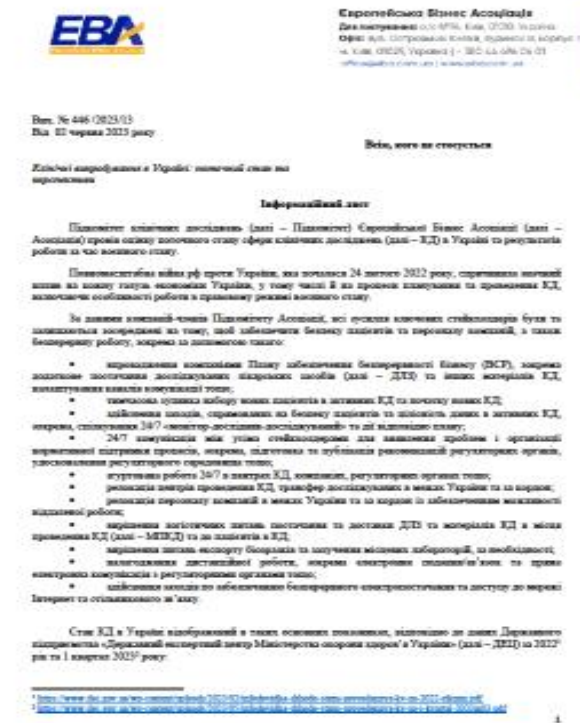
EBA
European Business Association

State support for CT recovery and development!

Communication directed at the world's leading pharmaceutical companies is the main tool for the recovery of the CT in Ukraine.

State initiatives - a strategic vision

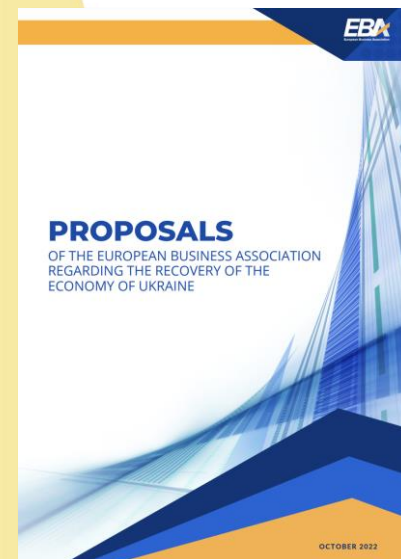
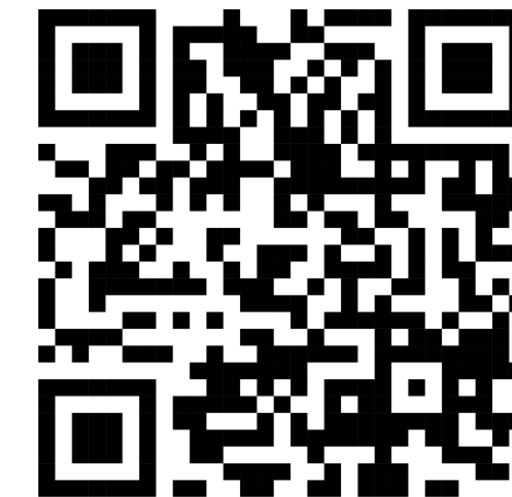
- [National Economic Strategy until 2030](#)
- [Recovery Plan for Ukraine in Healthcare Sector](#)
- [Strategy for the Development of the Healthcare System until 2030](#)



QR code for the EBA open letter in Ukrainian



QR code for the EBA open letter in English



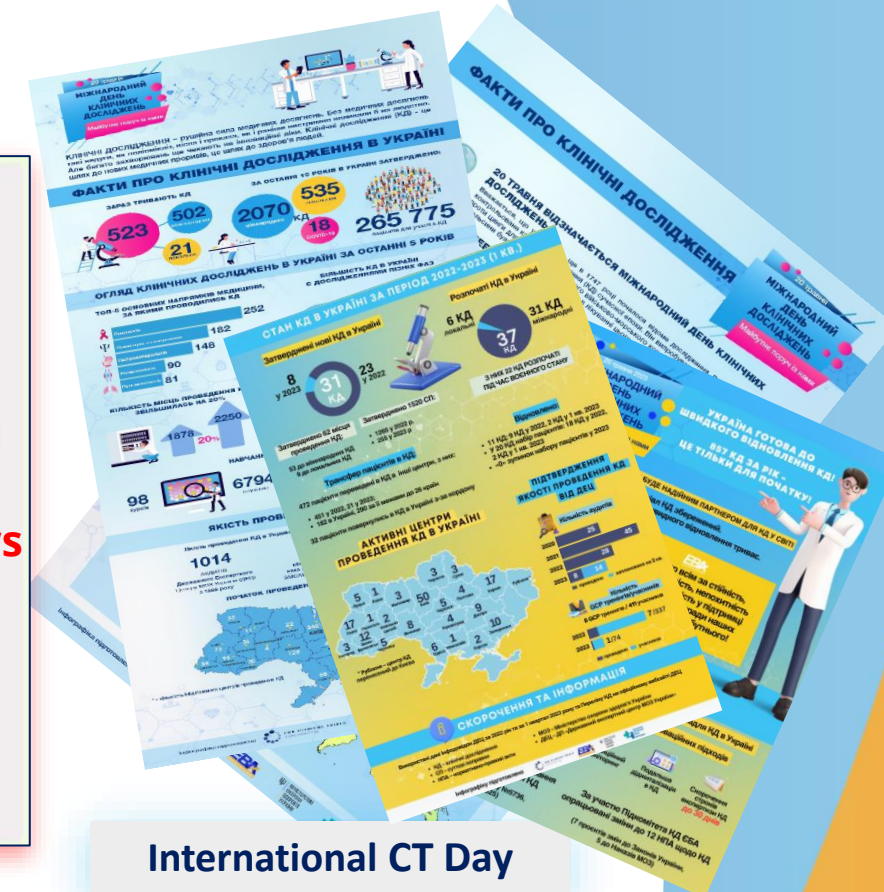
EBA vision:

- [EBA Guide to Reforms 2030](#)
- [Proposals of the EBA Regarding Recovery of the Economy of Ukraine](#)



'TRIALS TRUTH' CTS Informational Project

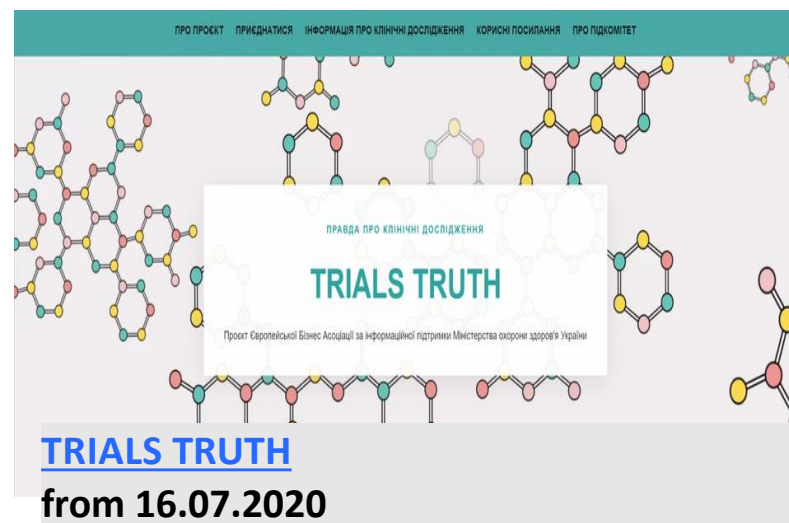
Implemented with the support of:



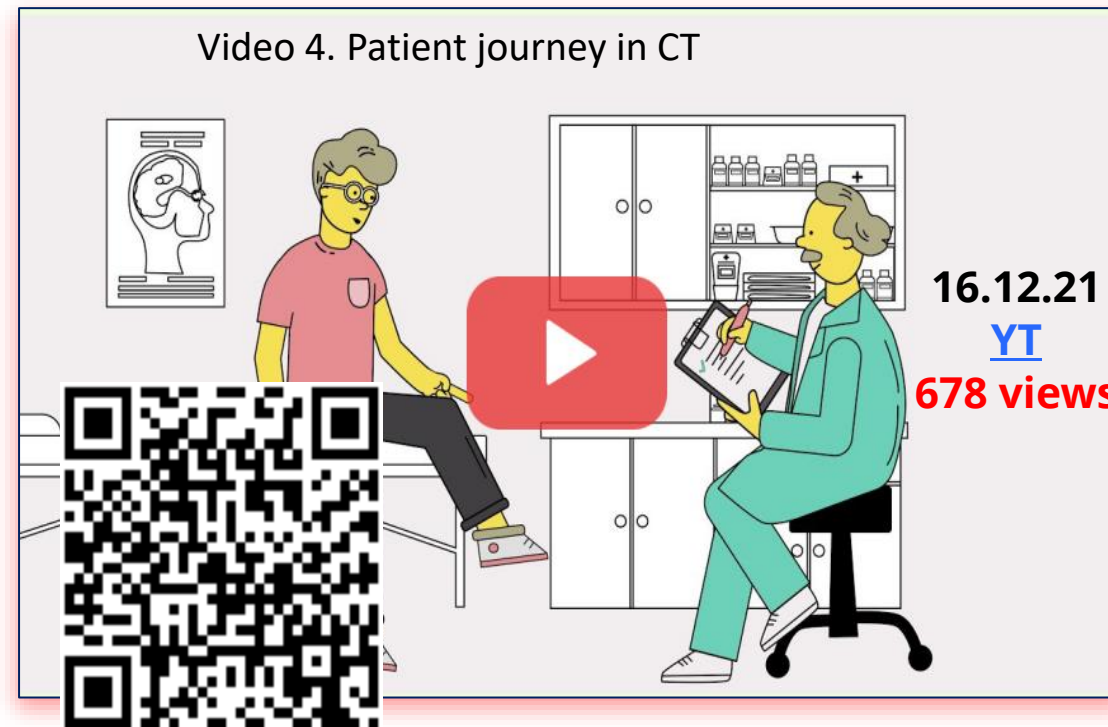
International CT Day



22.10.2019 [YT](#)
5,705 views



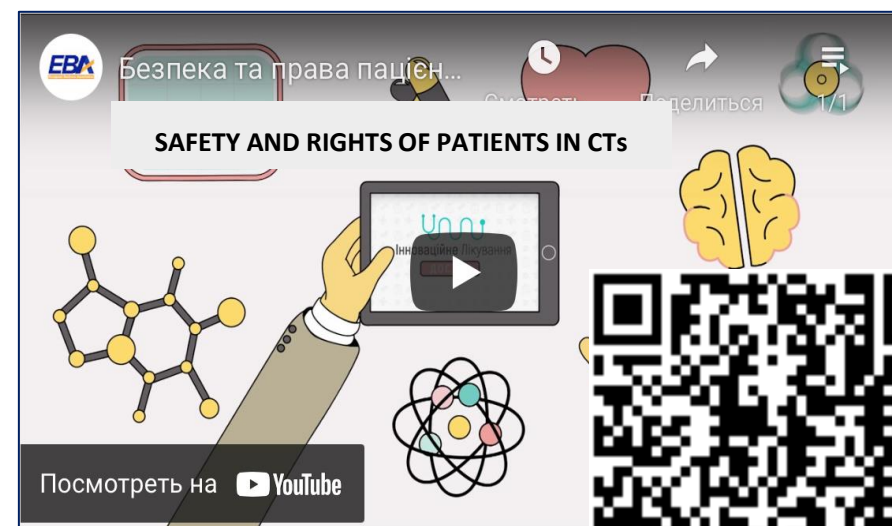
[TRIALS TRUTH](#)
from 16.07.2020



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07.10.2020 [YT](#)
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26.07.2021 [YT](#) 200 views



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