

Global cervical cancer: Clinical Trials 101

*Gynecologic Cancer Intergroup Cervical Cancer
Research Network*

Bucharest, Romania

February 3-4, 2018

Outline of talk

- Guidelines for global partnership in academic/public clinical research (OECD/CRIGH)
- Global communications & harmonization
- Essential elements for clinical research at the institutional level
- Essential elements for clinical research at the national/regional level
- Global networks/ intergroups

Organization for Economic Cooperation & Development Global Science Forum

- Initial proposal by Germany and Spain in 2008
- Working group from 20 countries; survey of OECD and BRICS
- OECD publications in 2011 & 2012



OECD Global Science Forum publications

- Facilitating International Collaboration in Non-Commercial Clinical Trials, 2011
- Recommendations on the Governance of Non-Commercial Clinical Trials, 2012
- www.oecd.org

Clinical Research Initiative in Global Health (CRIGH)

- Organized 2015-2016 as follow-up to OECD reports
- Joint secretariat shared by European Clinical Research Infrastructure Network, Paris, France & US National Institutes of Health
- Website: www.ecriin.org
- New members & observers welcome; modest dues for members
- Next annual meeting hosted by AMED, Tokyo, Japan: March 6-8, 2018
- Working groups: Infrastructure & funding, core competencies, patient involvement, ethics, & regulatory awareness

Outline of talk

- Guidelines for global partnership in academic/public clinical research (OECD/CRIGH)
- **Global communications & harmonization**
- Essential elements for clinical research at the institutional level
- Essential elements for clinical research at the national/regional level
- Global networks/ intergroups

Communications

- Scientific congresses, symposia, & workshops
 - Research prioritization
- Reading same journals
 - US NIH NLM Medline, etc
- Open database of clinical trials
 - Clinicaltrials.gov
- Visits, short-term exchanges, cross-border training & jobs

Harmonization

- Disease & cancer diagnosis (ICD-10, whobluebooks.iarc.fr); cancer staging (UICC TNM; www.uicc.org)
- Cancer evaluation & treatment
 - Molecular diagnostics, imaging, surgery, radiotherapy, chemotherapy, supportive care (anemia, mucositis, fatigue, etc)
- US NCI Common Toxicity and Adverse Events (CTCAE)
 - Patient-reported Outcomes
- US NCI Common Data Elements (CDE)
- Health-related Quality of Life instruments

Outline of talk

- Guidelines for global partnership in academic/public clinical research (OECD/CRIGH)
- Global communications & harmonization
- **Essential elements for clinical research at the institutional level**
- Essential elements for clinical research at the national/regional level
- Global networks/ intergroups

Institutional support for clinical research: I

- Commitment by institutional leadership to clinical research
- Protected time for doctors, physicists, nurses, pharmacists, etc for clinical research
- Recognition for accomplishments in clinical research in evaluation for performance, promotion, & salary
- Functional clinical trials office
- Functional and timely ethics committee

Institutional support for clinical research: II

- Robust informatics system & support for data managers
- Involvement of cancer survivors as advocates for clinical research
- Ongoing training on principles of clinical research
- Print, video, and social media communications for patients and their families about clinical research

Outline of talk

- Guidelines for global partnership in academic/public clinical research (OECD/CRIGH)
- Global communications & harmonization
- Essential elements for clinical research at the institutional level
- **Essential elements for clinical research at the national/regional level**
- Global networks/ intergroups

National/regional support for clinical research: I

- Timely and synchronized ethical, regulatory, & scientific review for clinical research proposals
- Financial support for clinical research infrastructure
- Financial support for individual clinical research projects/trials
- Insurance coverage for routine patient care costs
- Training about principles of clinical research in core educational curricula at schools of medicine, nursing, pharmacy, etc; master's level courses on clinical research
- Training for biostatisticians at bachelor, master, & PhD level

National/regional support for clinical research: II

- Partnership with cancer advocacy groups to promote clinical research
- Robust health informatics
 - To link individual patient data from clinical research studies with cancer registries, death registries, & other health care databases
- Regulatory framework for partnership with industry
 - Novel drugs, devices, imaging, RT equipment
- Regulatory framework for trans-border exchanges
 - Shipment of experimental drugs & devices; data sharing; shipping specimens to core laboratories, etc

Outline of talk

- Guidelines for global partnership in academic/public clinical research (OECD/CRIGH)
- Global communications & harmonization
- Essential elements for clinical research at the institutional level
- Essential elements for clinical research at the national/regional level
- **Global networks/ intergroups**

Global research networks/intergroups

- Financial and administrative support for secretariat
- Funding for specific clinical research projects/trials
- Regular meetings, conference calls, & email/text communications; publications guidelines & committee
- Robust global informatics & data management system
- Core laboratories
- Infrastructure for distribution of experimental drugs & devices
- System for QA/QC for imaging, cancer therapy, supportive care

Outline of talk

- Guidelines for global partnership in academic/public clinical research (OECD/CRIGH)
- Global communications & harmonization
- Essential elements for clinical research at the institutional level
- Essential elements for clinical research at the national/regional level
- Global networks/ intergroups

Thank you for your attention

- Edward L. Trimble, MD, MPH
Email: tt6m@nih.gov
Twitter: [@NCITedTrimble](https://twitter.com/NCITedTrimble)
Website: www.cancer.gov

