(WHY) DO WE NEED HARMONIZED TRAINING STANDARDS?

Jean-Pierre Tassignon, MD, PhD, FFPM
President and CEO, Crossover CRI AG, Zug, Switzerland
Lecturer and Examiner, Pharmed PG Course in Pharm Med, ULB, Brussels
Visiting Professor, Head of the Clinical Research Unit, CHU Brugmann &
Queen Fabiola Children‘s Hospital, Brussels

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(WHY) DO WE NEED HARMONIZED TRAINING STANDARDS?

- FIRST COME THE RESPONSIBILITIES
- ALL THOSE INVOLVED HAVE RESPONSIBILITIES
- TODAY: THE CONFUSION OF LANGUAGES
- TRAINING HELPS HARMONIZING IMPLEMENTATION
- EXAMPLE: INVESTIGATOR TRAINING
- THE WAY FORWARD

FIRST COME THE RESPONSIBILITIES

ICH-GCP defines the responsibilities of

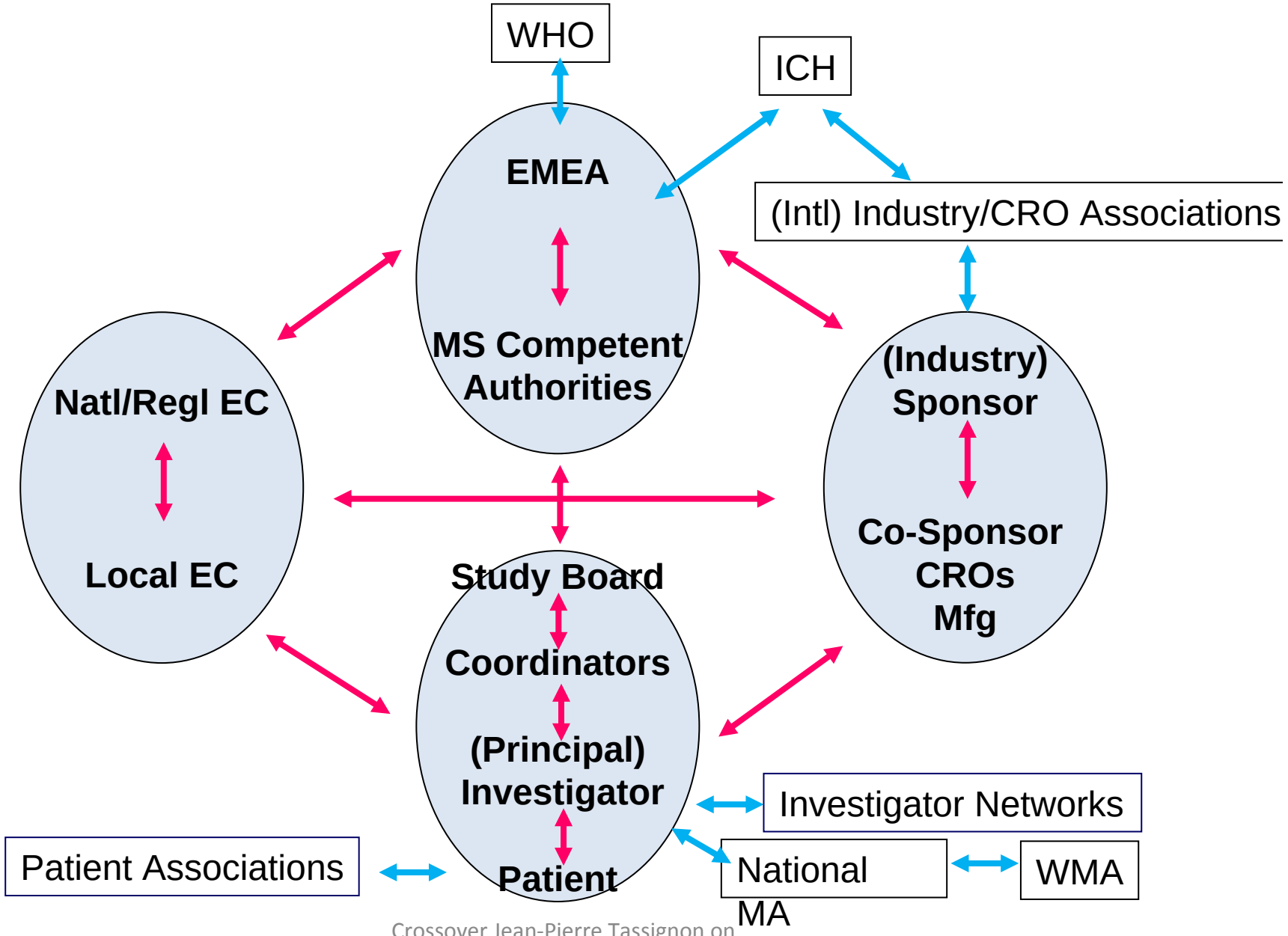
- ETHICS COMMITTEES
- INVESTIGATORS
- SPONSORS

Missing:

- PATIENTS
- REGULATORY AUTHORITIES

Harmonized responsibilities do not mean harmonized implementation.

ALL THOSE INVOLVED HAVE RESPONSIBILITIES



XIXth c engraving by Gustave Doré

TODAY: THE CONFUSION OF LANGUAGES

Sponsors/CROs: different budgets, different CTA‘s, different protocol layouts, different procedures for feasibilities, initiation, routine monitoring, SAE reporting, different (e)CRFs, different procedures for query resolution, etc.
Ethics committees: different composition, bylaws, forms, reports, judgments, etc.
Sites: different diplomas, SOC, ways of informing patients, judgment on in-/exclusion criteria, organization, governance, recordkeeping, HIS, etc.

Interdependent individuals involved in clinical trials
knowing their respective responsibilities
expect predictable interactions

TRAINING HELPS HARMONIZING IMPLEMENTATION

For whom? What? How much? When? How long? By whom? Where? Who pays? etc.

There are already a myriad of educational events in all possible formats:

- eLearning in modules, including quizzes and certificates
- Post-graduate courses
- Journals
- Presentations at investigator meetings and initiation visits
- Etc.

TRAINING REQUIREMENTS ARE ILL-DEFINED

Declaration of Helsinki (1964-amended 2008)	ICH-GCP (1996)	EU CT Directive (2001-implemented from 2004)
16. Medical research involving human subjects must be conducted only by individuals with the approriate **scientific** training and qualifications	Principle 2.8* Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s)	Article 3.3 The **medical** care given to, and **medical** decisions made on behalf of, shall be the responsibility of an appropriately qualified doctor

* See also identical text in GCP Directive 2005, Chap 2, Sec 1, Art 2, 2

➢The training obligations are scientific (DoH) or medical (CT Directive) or related to tasks in the study (GCP).

EXAMPLE: INVESTIGATOR TRAINING

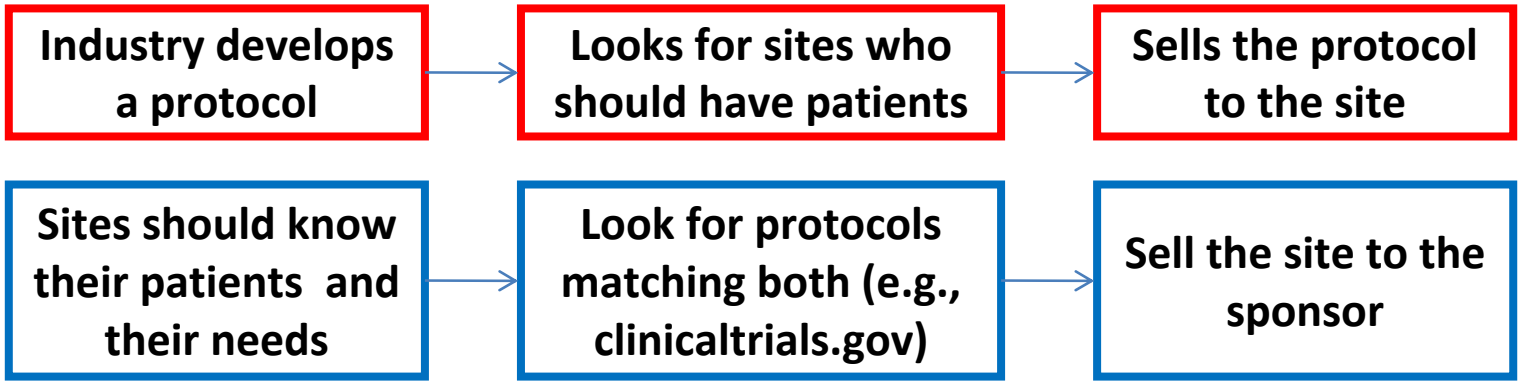
In general, investigators are succesful scientists. **Scientific training is not what they need.**

Training in relation to CT must teach investigators **how to become successful investigators**:

a) Identifying the right trials for them
b) Successful budgeting and negotiation of the CTA
c) Building and motivating an investigative team
d) Linking colleagues inside and outside the hospital for referrals
e) Identifying the right patients for the study
f) Consenting patients effectively
g) Conducting the trial according to the protocol
h) Handling the information flow and paper mountain.

This training CANNOT be designed/given by people who do not have investigator experience.

A. IDENTIFYING THE RIGHT TRIAL(S)



Corollary: A sponsor/CRO should send most/all its protocols to the CRU of the hospital, and the sites should chose the best fit.

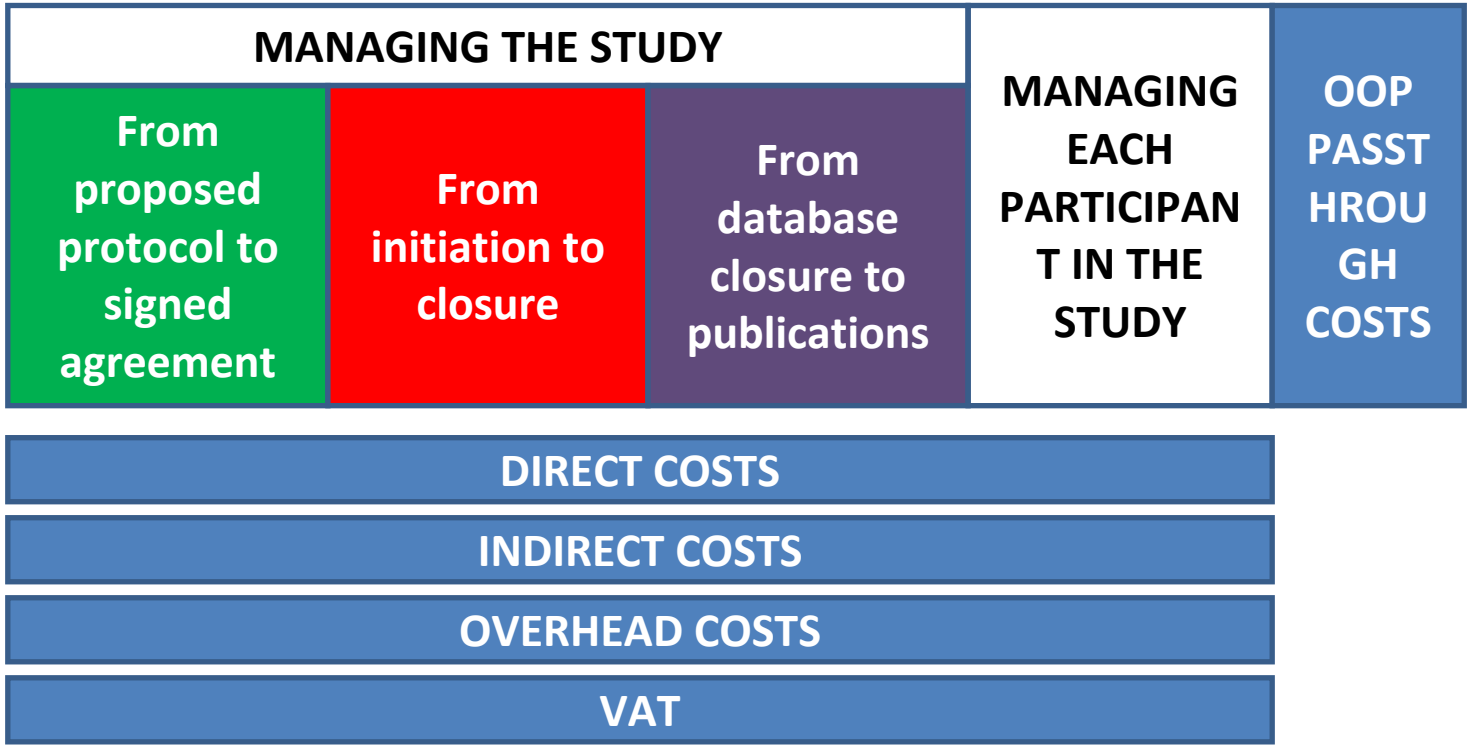
In an ideal world,
- Investigators develop/maintain databases of potential study participants.

But, this
- Requires costly software,
- Is opposed by ethical rules/privacy laws,
- Activity is not financed,
- Requires an endless reprogramming of categories as a function of taxonomy,
- Is defeated by the proliferation of in-/exclusion criteria,
- Given healthcare staff and patient mobility, requires trans-institutional databases.

B. SUCCESSFUL NEGOTIATION

B. SUCCESSFUL NEGOTIATION (CONTINUED)

Sites do not know how to budget CTs



OTHER TRAINING NEEDS OF INVESTIGATORS

-Building and motivating a team
-Linking inside and outside the healthcare institution for referrals
-Identifying the right patients
-Consenting patients effectively
-Conducting the trial according to the protocol
-Handling the information flow and paper mountain.

THE WAY FORWARD

Industry/CRO approaches to training sites have failed to make investigators successful in running CTs. Industry sponsors offer training into formal procedures with no funding and no certification, yet 13 industry sponsors control 50% of all CTs in clinicaltrials.gov

Sites need to identify their specific training needs ASAP, develop the material, train the trainers and find the funding and certification.

The EU or the Member States and Patient Associations should be concerned about empowering investigators. Let's start with their institutions.