Scientific Evidences in Homeopathy: a dynamic database

Introduction. Rationale. Instructions for use

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1. Scientific Research in the era of EBM

Since the early 1990s, EBM (evidence-based medicine) has redefined the parameters for scientific research, especially in biomedicine, as well as those of professional practice. In this sense, the quality of clinical study has become crucial both in patient management and health policy choices. The quality of a clinical study must generally take account of 10 aspects:

1. *Description of the characteristics of enrolled patients*
2. *Study design*
3. *Patients sample size*
4. *Description of the randomization*
5. *Blindness*
6. *Treatment description*
7. *Description of measurement modes*
8. *Patients who completed the study*
9. *Statistical suitability*
10. *Type of medical team*

The study must also be published in a peer reviewed journal, meaning that it must be assessed by a committee of referees. The journal must be indexed in biomedical databases (PubMed, Scopus, etc.) and it may have an Impact Factor (I.F.)

2. Scientific Research in Homeopathic Medicine: peculiarities and criticalities

One of the objections that has always been raised against homeopathy is the "lack of clinical evidence", fruit of deficient or poor scientific research. Its therapeutic effect would therefore be imputable to the placebo effect. Yet, historically, homeopathy was developed under the sign of research and experimentation: Hahnemann, was in fact the first physician to ever test and rigorously catalogue the symptomatology produced by the pure action of substances on a healthy subject to then use it therapeutically on a patient. Following its teachings, other homeopaths tested the actions of medicinal products with double-blind and multi-center study techniques, long before the development of clinical trials. In terms of methodology, the leap in quality research in homeopathy dates to the 1970s-80s when a series of studies with more stringent criteria started to be produced. With the advent of the EBM culture (1991-92), scientific production has substantially increased both quantitatively and qualitatively, especially over the past decade. However, for the purpose of correct evidence evaluation, it is fundamental to take account of the peculiarities and criticalities proper of homeopathy, such as:

- The personalization of the treatment and modulation of posology vis-à-vis the practice of protocols usually adopted by "conventional" research which, on the contrary, tend to disregard individual differences.
- The dilutions used, where the remedies are often so diluted that they become undetectable in pharmacokinetic analysis, unless extremely sophisticated equipment is used.

Finally, the issue of research-associated costs is not insignificant, nor is that of Ethical Committees or of the journals which not infrequently reject studies on homeopathy, often based on bias.

3. A Dynamic Database: rationale

To show the existence and value of scientific research in homeopathy, a "DYNAMIC DATABASE", namely a constantly updated database, was created (http://databaseomeopatia.alfatechint.com/). Below the inclusion/exclusion criteria (Tab. 1)

Tab. 1

Inclusion Criteria:	Exclusion Criteria:
– Studies with homeopathic medicinal products published and indexed (since 1949) – It includes both positive and negative studies – References drawn from: Pubmed, Embase, SCOPUS, Core-Hom and Google Scholar; – For each reference included: relevant **link** to the abstract (sufficient and necessary condition);	• Studies with CAM in general and/or mixed studies (with homeopathic medicinal products and CAM); • Books, conference proceedings, • Journals not accessible via Internet, • Posters, • Educational magazines, • Publications with editorial discretion • Publish and Perish; • Currently being reviewed (comments, Brief Notes)

Research in homeopathy has developed into various fields, thus the database was organized accordingly based on the relevant areas of interest:

- Agro-homeopathy: it uses homeopathic medicinal products on plant models (plants in greenhouse, opengrown plants). It is based on standardized, quickly applicable, relatively inexpensive experiments, without ethical implication or placebo effect.
- Basic Research (chemical-physical): it studies the chemical-physical properties of extremely diluted solutions (EDS) where the diluted is dissolved into the solvent.
- Preclinical Research (lab): it studies possible mechanisms of action of homeopathic medicinal products through "in vitro" or "in vivo" models
- Case Reports: individual clinical cases of patients treated with homeopathic medicinal products
- Clinical Research (observational or non-interventional studies): it explores the clinical effect of homeopathic medicinal products observing the evolution of the disease/medical condition in response to the pharmacological therapy prescribed.
- Clinical Research (RCT or interventional studies): it explores the clinical efficacy of homeopathic medicinal products compared with placebo or with a control drug.
- Qualitative or Narrative Systematic Reviews: collection of clinical studies describing the studies included in the review with a qualitative and/or narrative approach.
- Systematic Reviews with Meta-Analysis: it analyzes the results of a series of clinical studies answering a specific clinical question thus establishing, statistically, the efficacy of the pharmacological therapy under study.
- Veterinary: it assesses the clinical and experimental efficacy of homeopathic medicinal products in farm and/or pet animals diseases.

4. Study Quality:

To assess the quality of the studies, evaluation scales are generally used where scores are collected and assigned to the parameters analyzed, such as, for instance, study design, optimal conduct of the

research under scrutiny, reporting quality and completeness of the description of the study for publishing purposes.

STUDY DESIGN	QUALITY CHECK LIST	REPORTING CHECK LIST
GUIDELINES	GRADE	
SYSTEMATIC REVIEW WITH META-ANALYSIS	AMSTAR	PRISMA
RCT	JADAD SCALE	CONSORT
CONTROLLED NON-RANDOMIZED STUDY		TREND
COHORT STUDY	NEWCASTLE-OTTAWA SCALE	STROBE
CASE-CONTROL STUDY	NEWCASTLE-OTTAWA SCALE	STROBE
LONGITUDINAL STUDY		STROBE

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5. Database: instructions for use

All the studies included have been provided with "masks" to search for the main reference parameters of the study (Tab. 2-3):

Tab. 2

Year of publication	First author	Journal	Page/Volume
Title	Type	Keywords	Link to abstract/full text

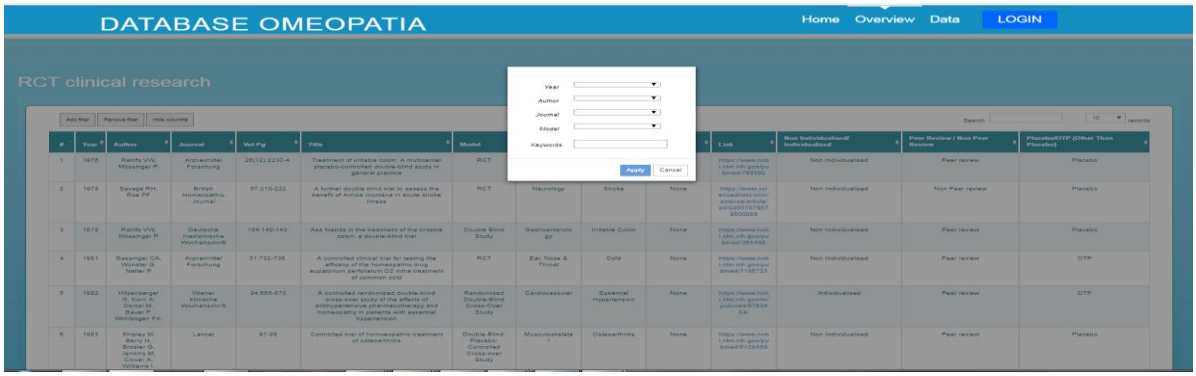
Tab. 3

For RCT studies, other masks were added, referring to:

- Pathological condition studied
- Therapy with homeopathic medicinal products, individualized or not
- Publishing on peer reviewed journal, or not
- Comparison with placebo or OTP (Other Than Placebo)

Filters were added (add filter) to make it easier to launch "historical" queries (e.g. since the year …), or by Author, Journal, Design, Keywords (Tab. 4)

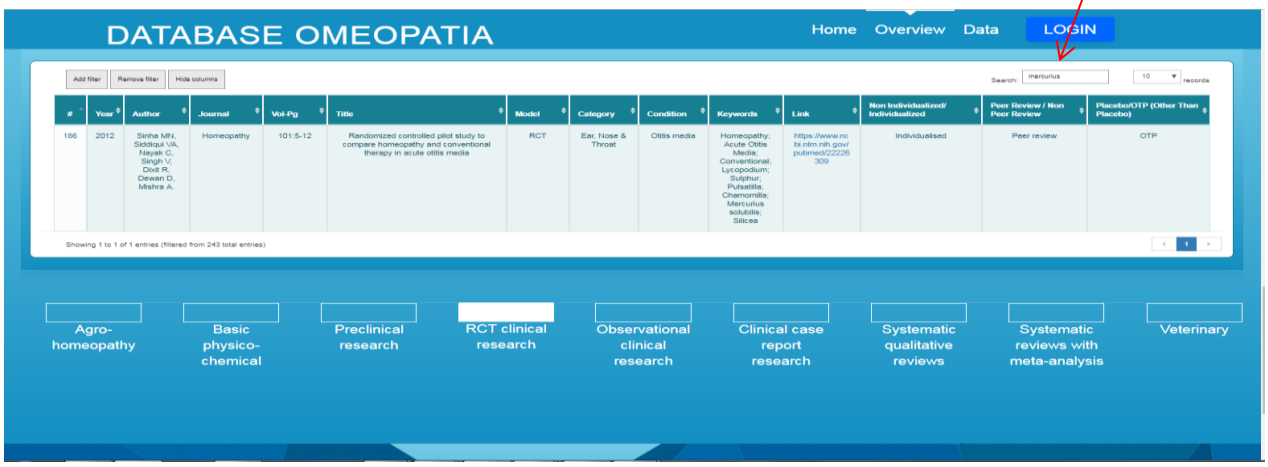
Tab. 4



You can also sort by:

- medicinal product, in the different sections, by clicking in the top right box ("Search"). E.g.: Mercurius (Tab. 5)

Tab. 5



- category (specialization), study design, pathological condition, etc. by clicking on the relevant column (Tab. 6):

Tab. 6