



**Good Practice in Traditional Chinese Medicine Research in
the Post-genomic Era**

GP-TCM

223154

**Handbook on Good Practice in the reporting of
CHM experimental work**



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Abstract	The document is aimed at researchers in the field of <i>in-vitro</i> pharmacology using Chinese herbal medicine. It is intended as a "HelpBook" with guidelines on how to report experimental work according to good practice, as established by research and discussion carried out by WP4 members.
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1 HANDBOOK ON GOOD PRACTICE IN THE REPORTING OF CHM EXPERIMENTAL WORK

1.1 Preface

The Good Practice in Traditional Chinese Medicine Research in the Post-genomic Era (GP-TCM) consortium was launched by the European Commission on the 1st May 2009. This is a three-year coordination action project funded under the EU Seventh Framework Programme (FP7) with a total budget of €995,100. The central hypothesis of the consortium is that, using functional genomics technology, and furthermore linking them to clinically relevant biological functions, we might be in a better position than ever before to interpret and validate the scientific value of TCM in a holistic and function-oriented manner. WP4 was established to look into, among other things, good quality reporting of scientific findings in the area of *in-vitro* pharmacology. This publication will be updated annually with new inputs.

1.2 Problems in presenting the results of TCM *in-vitro* experimental work

In-vitro research of herbal preparations has been hampered by the wide array of biological effects of the complex and variable mixtures of chemicals obtained from extracts (phytocomplexes). The reductionist approach of characterising single bioactive molecules from phytocomplexes has thus proven disappointing. The biological effects of phytocomplexes are thus poly-pharmacological and represent a synthesis of several different effects exerted by clusters of molecules acting simultaneously, in synergy or in antagonism, on different molecular sites. Emerging functional genomics approaches, which combine activity assays, genomics, proteomics, metabolomics, *in-silico* biology and bioinformatics methods, produce a wide array of simultaneous observations and bring in an innovative, more “holistic” approach to herbal studies. Crude herbal drugs and particularly Chinese formulae are natural products and their chemical composition varies depending on several factors, such as the geographic source of the plant material, the climate in which the plant was grown, and time of harvest. Commercially available herbal medicinal products also vary in their composition, both quantitatively and qualitatively, from batch to batch. Even when herbal products are standardised for content of known active or marker compounds there is variation in the concentrations of other constituents that can result in differences in pharmacological activity *in vitro*.

Moreover, for Chinese herbal medicines, the names used in the literature are very variable. The same medicinal plant products can be described using different terms, including Latin binomials, pharmaceutical names, English names, simplified and traditional Chinese characters, Chinese Pinyin names, names in Japanese and other Asian languages and their different English transliterations. Different translations are also involved in the description of the medicinal parts of the herbs, processing, cooking and extraction methods, types of preparation, composition of *Fufang* (herbal remedies comprising more than two TCM products) and doses of individual TCM products. More complicatedly, some Pin Yin, pharmaceutical names and any non-standardised names might refer to different species of herbs (*GP-TCM SOP manual*).

Also, preparation methods vary significantly (including the means of extraction, if any; whether the material is heated for a prolonged period, etc) which could also contribute to variability in chemical composition and hence pharmacological activity *in vitro*.

1.3 Guidelines for reporting *in-vitro* CHM experimental work

The following guidelines have been established by an exploratory phase of analysis involving WP4 members consisting of evaluation using different sets of criteria. As a result of this preliminary work, the guidelines below are currently suggested and will be refined over time and



updated on the website where each user/reader can write his/her comments and opinions which will be taken into account for subsequent revisions.

- These criteria apply only to studies dealing with phytocomplexes or other mixtures of biologically active compounds for in-vitro research;
- Studies on purified compounds follow the roles of any other scientific paper;
- The paper has to be published in a journal that is abstracted by Pub Med database;
- These criteria have been drawn up from consideration of articles written in the English language.

1.3.1 Nomenclature

For Chinese herbal medicines, the names used in the literature are very variable. Some general principles on naming Chinese medicinal plants are proposed (*WP1 (D1.4) and SOP, section 6.3 of the Standard Operating Procedures [SOP] of GP-TCM Literature Reviews*):

- The English Common name (e.g., Scute for *Scutellaria*) should be avoided as far as possible as it is too variable and may lead to confusion. If it is used in literature searches then some additional identification of the herbal drug in the papers that are retrieved is essential;
- The use of Latin binomials contributes to scientific rigour. However these can only be used if the plant material or herbal drug has been fully authenticated by an appropriate botanist;
- The Latin binomial only applies to the plant; the part of the plant and details of processing must be added if referring to the herbal drug;
- If only the Pin Yin or other transliterated name is given in a paper without any botanical authentication then the Latin genus and species cannot be assumed;
- Construction of Pharmacopeial names: these names should not be confused with Latin binomials (which regularly happens on web sites!) and are designated as follows: Latin word designating the considered organ + Latin name of the plant (often only the genus is indicated) declined as a Latin genitive (this is the Latin termination that denotes "of").

1.3.2 Title and abstract

The title or abstract or both should provide the herbal medicinal product's:

- Latin binomial name of the plant (or clear name of the product). It is emphasised that this information should be in either the title or the abstract even if the information is provided in the text of the article;
- The part of the plant used;
- The eventual particular processing applied to the plant;
- The experimental use of the plant/product;
- An accurately described summary of the article's contents.

1.3.3 Introduction and background

The scientific background should be presented here including the following components:

- An explanation of the rationale, including a brief statement of the reasons for the study with reference to the specific herbal medicinal product and its traditional use;
- A statement reflecting whether the study is new, building on existing knowledge or whether traditional indications are being investigated.



1.3.4 Objectives

The specific objectives and hypotheses of the study should be clearly presented here. It is emphasised that this information should be separately presented (if the required format of the journal permits it) even when, depending on the journal, it might be found elsewhere in the paper. The objectives and hypotheses should reflect the actual experimental approach used in the study.

1.3.5 Method

This section is divided into two different subheadings, plant description and experimental methodology.

1.3.5.1 Methods – (plant description)

There are GENERAL criteria which apply to all articles and others which refer to the specific type of preparation used.

General: The methods should describe:

- The method of authentication of the herbal raw material indicated;
- Solvent used and ratio for the extraction;
- Time of extraction;
- Temperature of extraction;
- Yield of extraction;
- Details of any voucher specimen must be included;
- The test material should have been subjected to simple chemical constituent profiling and/or complex fingerprinting. The methods used should be described as well as the service, if applicable;
- The material should have been standardised (by what process and by whom), if appropriate and possible.

Specific: In the case of unprocessed plant and/or mixtures of plants, there are two extra criteria:

- The herbal product name should be clearly indicated;
- The part of the plant used to make the product should be specified.

Specific: In the case of processed plant and/or mixtures of plants, there are five extra criteria and guidelines:

- The processed products names or the extracts names and the name of the manufacturer of the products should be indicated;
- The batch number of the herbal products should be indicated;
- The parts of the plants used to make the product or the extract should be specified;

Where applicable:

- The type of preparation to make the test material should be described;
- The yield of the extraction to make the test material should be indicated.

Specific: In the case of a proprietary product, there are five extra criteria:

- The proprietary product name or the extract name and the name of the manufacturer should be indicated;
- The batch number of the product should be indicated;
- The part of the plants used to make the product or the extract should be indicated;
- Where applicable:
 - The type of preparation to make the test material should be described;



- The yield of the extraction to make the test material should be indicated.

1.3.5.2 Methods (experimental procedure)

Five guidelines should be taken into consideration:

- The details of administration/application of test material(s) should be described
- The test system should be of relevance for TCM studies (human enzyme, human cells, etc...);
- Proper controls should have been used;
- Quality controls and/or characterization of model(s) should have been performed;
- A description of and justification for the statistical methodology used should be given.

In this section, some suggestions are made relating to extra guidelines involving experimental design and procedure as well as general strategy which can be considered useful when dealing with *in-vitro* CHM research as examples of best practice using a more systems biology-orientated approach:

Protocols:

- Multiple protocols
- High throughput analysis/microarray studies

Test systems:

- Multisystemic cell components, or cell-based tests, as examples
- Co-cultures particularly if human
- Tissue culture particularly if human
- Whole blood particularly if human
- Isolated organs particularly if human

Other:

- Appropriate *in-silico* models
- Supplementation of data by *in-vivo* tests
- Supplementation of the data by clinical findings

1.3.6 Results

Seven guidelines should be taken into consideration:

- It should be clear that $n \geq 3$;
- The sample size should be appropriate;
- Adequate controls should be used;
- Outcome measures should be clearly defined;
- The test results should have been appropriately used in the statistical analyses;
- The significance should be clearly shown in figures and tables;
- Data should provide evidence of selectivity of biological effect and its specificity.

1.3.7 Conclusion and Discussion

The conclusions of a study should be honest, whether or not an activity is found. Both results are in fact equally important for the future scientists as they help them to plan their research. Four guidelines should be taken into consideration:

- Conclusions should reflect the results and an emphasis should be given to robustness;
- The results should be appropriately interpreted in light of the product test dosage regimen used;



- The conclusions should be linked to clinical use, when appropriate. Particular attention should be paid to the concentration used, bearing in mind that often in-vitro results obtained at a certain concentration are meaningless for in-vivo situations.
- In the conclusions there should be an indication of previous work and a statement regarding the support or contradiction of such existing data.

1.3.8 Conflict of interest

Good quality papers should include a declaration relating to potential conflicts.

1.3.9 Bibliography

Bibliography should be according to the policy of the journal.