

Standard Operating Procedures (SOP) of GP-TCM Literature Reviews

Annex 1

Central Questions of GP-TCM Work Packages

1. WP1- Quality Control of CHMs

Deliverables	Questions
D 1.1: Preliminary list of species	<ul style="list-style-type: none"> • What criteria are used to select species • How many species • What names are used to describe species • What data per species will be gathered • Have the team the expertise to gather all data required: chemistry, traditional use, good agricultural practice, frequency of use, etc.
D 1.2: Web site	<ul style="list-style-type: none"> • What topics are covered for quality control • What is the format of the site: headings that can be used to assist collate relevant information • How do we link among data in different websites • What level of detail will be entered and how will we track ownership of data being gathered • How are tasks allocated so that all agreed topics are covered • How do we co-ordinate information among workshop web sites
D 1.3 Priority list of species	<ul style="list-style-type: none"> • How many species do we target • What criteria are used to priorities among species • How do we link the lists from the different Work Packages • Who decides what the final list of key species will be • When should this list be defined
D 1.4 Database that link plant names	<ul style="list-style-type: none"> • How best to link the different names given to the selected species • What procedures would support best practice in the standardization of naming TCM species used in products
D 1.5 Workshops	<ul style="list-style-type: none"> • How do we co-ordinate workshops to maximise data gathering activities for each of the agreed topics so that the agreed timetable can be met • Will the workshops be able to identify gaps in our knowledge • How do we gather more data from within China on aspects of quality control associated with Good Agricultural Practice
D 1.6 Procedure for good practice in quality control	<ul style="list-style-type: none"> • What is considered to be a good quality control standard practice for a TCM product • Do we take what is required for the EU Directive on Traditional Medicines
D 1.7 Identify Knowledge gaps	<ul style="list-style-type: none"> • What standards are we aiming to meet • What methods could be used to obtain the data
D 1.8 Identify vouchers for the species	<ul style="list-style-type: none"> • Which institutes in EU and China have voucher samples for selected species and any associated substitutes and possible adulterants • Will we be able to cite reference numbers to the vouchers so that others can make reference to these samples
D 1.9 Overview report	<ul style="list-style-type: none"> • What will be the target audience for this report • What information is required and what tasks are needed to collate the data in an agreed format • How will we evaluate whether the report is of use to the agreed target audience
D 1.10 Final Report	<ul style="list-style-type: none"> • What key points will be included and what format • Do we link the report directly to the requirements of the EU directive on herbal medicines • Do we link the report to other international initiatives on further the understanding of the trade of medicinal plants
D 1.11 Scientific papers	<ul style="list-style-type: none"> • Which journals will be targeted for publication of papers on the challenges and solutions for the quality control of TCM • Can we get any of the data incorporated into policies/documents being produced within Europe or China on quality control of plants

2. WP2- Extraction and Component Analysis of CHMs

Deliverables	Central Questions
D2.1, D2.2 Kick off meeting and Priority list of CHM species	<ul style="list-style-type: none"> • What TCM products are of outstanding importance for the EU? (Krenn, Sheridan) • Which clinical indications should be used starting points? (Krenn, Sheridan) • Are there important criteria that cannot be covered using clinical indications as a starting point? • Will the target list contain single drugs, drug combination, and plant species...? • What criteria can be used for the selection of TCM drugs? • How many entries?
D2.3 Website	<ul style="list-style-type: none"> • How will the data be gathered and collated on the website or another web-based platform in order to maintain easy access and online-collaboration to the WP? • What is the format of the site: headings that can be used to assist collate relevant information? • How can we use the web-resources to collate data (e.g. standardised headings in WIKI monographs)? • What level of detail will be entered and how will we track ownership of data being gathered? • What topics do we want to have addressed on the public part of the website?
D2.4 Report summarising analytical techniques	<ul style="list-style-type: none"> • What techniques are currently in use for the analysis of TCM drugs? • What standards are currently used for analysis of TCM drugs? • Which kinds of separation materials are suitable for extraction and preparation of CHM components in different polarities? • How to establish a unique database for fast target screening of analytical result? • What kind of information is to be collated with regard to forthcoming deliverables, especially D.10?
D2.5 Report summarising extraction	<ul style="list-style-type: none"> • Will <i>paozhi</i> techniques be considered here? • Will we consider extractions for medical use or analytical purpose or both? • What techniques are currently in use for extraction and component analysis of TCM drugs? • What standards are currently used for extraction of TCM drugs? • Which extraction techniques are suitable to be suggested (required) for a reproducible production of extracts? • Which kinds of separation materials are suitable for extraction and preparation of CHM components in different polarities? • How to implement CCC techniques? • What kind of information is to be collated with regard to forthcoming deliverables, especially D.10?
D2.6, D2.7 Workshop and Report: "Minimum acceptable standards"	<ul style="list-style-type: none"> • Which analytical techniques and standards can be required for TCM extracts with respect to European legislation and consumer protection? • Are there TCM specific properties that are not covered by European regulatory requirements? If so, should these properties be covered in the future? • What data are to be collated in D2.4, D2.5 and D.10 in order to evaluate the status of a specific TCM drug with regard to minimum acceptable standards (existing and newly-defined)?
D2.8, D2.9 Workshop and report "Information analysis"	<ul style="list-style-type: none"> • What modern techniques for extraction and component analysis can facilitate the research on TCM drugs with special respect to discrepancies between current status (D2.4, D2.5) and minimum acceptable standards (D2.7)? (e.g. supercritical fluid extraction, microwave assisted extraction, hyphenated techniques, multivariate statistics)?

D2.10 Comprehensive report on methodology	<ul style="list-style-type: none"> • What data of the priority list species needs to be collated for this report? • What data can be extracted from D2.4 and D2.5 • How can this deliverable be best used as a base for the final deliverables (D2.13-D2.15)? • How to design this deliverable for an easy comparison with the minimum acceptable standards (D2.7)?
D2.11, D2.12 Workshop and report: "Correlation of current methodology with recommended best practice, recommendations for research agenda"	<ul style="list-style-type: none"> • Where are gaps of knowledge for priority list species with special respect to the minimum acceptable standards? • How can modern techniques be best applied in order to facilitate the research on the identified gaps? • How to correlate the outcome of our compilations and reviews to the existing European legislation for herbal medicinal products?
D2.13 Conference Presentation	<ul style="list-style-type: none"> • What will be the target audience?
D2.14 Final report, database of experts and distribution of skills.	<ul style="list-style-type: none"> • What key points will be included and what format? • What skills will be monitored for the expert database?
D2.15 Review Paper	<ul style="list-style-type: none"> • Is there need/opportunity to issue further review papers beside the J. Ethnopharmacol. review which has already been planned? • If so, which journals will be targeted?

3. WP3- Toxicology of CHMs

Deliverables	Central questions
D3.1 Kick-off meeting	<ul style="list-style-type: none"> • Does anyone have questions about the GP-TCM project in details? • What are the milestones and potential problems in WP3? • How the mandatory deliverables will be delivered on time and in high quality?
D3.2 Website	<ul style="list-style-type: none"> • What structure, contents and features are needed for the WP3 web page?
D3.3 Systemic literature review & translation	<ul style="list-style-type: none"> • What is the SOP for literature review and translation? • What are the current status of research on toxicology, adverse effects and safety of TCM products, including neuro-, nephro-, hepato-, geno-toxicity, drug-drug interaction, etc? • What is the gap of knowledge in these areas of research? • What do official documents of EMEA and other governmental bodies tell us concerning the regulation of CHMs/phytomedicines safety?
D3.4	<ul style="list-style-type: none"> • Website update and maintenance
D3.5 D3.5.1 web-based Workshop 1 D3.5.2 Initial report	<ul style="list-style-type: none"> • What preparation do we need for organising a workshop reviewing information on the current state-of-art methodology used in assessing the toxicity of CHMs? • What do we expect from such a workshop? • What can we conclude based on available toxicological information related to CHM products, including: priority list for widely used herbs, toxic or potentially toxic herbs, toxic components, potential target organs and toxicity mechanisms, as well as the potential interactions between CHMs and orthodox products? • What are the existing 'omics methods and models for toxicity evaluation of CHMs?
D3.6 D3.6.1 web-based Workshop 2 D3.6.2 Mid-term report	<ul style="list-style-type: none"> • Through a workshop, any conclusions on review outcomes on the toxicological data compiled during the project? Any prospects? • What can we conclude on the techniques and models employed for the evaluation of CHMs? What are the gaps of knowledge? What are its strength and limitations in the context of all other methodologies? • In which areas are emerging new techniques, especially functional genomics, have a promising application? • Through the studies in the past two years, any recommendations for best practice in toxicology evaluation of CHMs products?
D3.7 Final WP meeting (web)	<ul style="list-style-type: none"> • What information is required and what tasks are to be undertaken to produce a report that can be presented at the Project Final Conference?
D3.8 EU Report	<ul style="list-style-type: none"> • What key points are to be included and which format is to be chosen in the final report to the EU? • What areas are required by the European Directive on herbal medicines for their monographs? • What are the collective findings of WP3? • Any recommendations and directions for future research in assessing the toxicity of CHMs?
D3.9 Publication	<ul style="list-style-type: none"> • Which journal and which format are to be used for publication of paper(s) on the current status, challenges, solutions and priorities for the toxicology studies of TCM products? • 2) Any additional questions need be addressed for publication purpose?

4. WP4-In vitro pharmacology

Deliverables	Central Questions
D4.1: Kick-off WP4 meeting	<ul style="list-style-type: none"> • What should the phase I kick-off meeting discuss? • What are the milestones and potential problems in WP4? • How should the agenda be organised in order to assure all the deliverables will be given on time and in high quality? • What are the tasks of the work package and how should this be reflected in the composition of the subgroups? • Should WP4 focus on selected research areas, and which criteria should be used to choose them? • How should the issue of rating publications in the area of in-vitro studies on traditional Chinese medicine be addressed? • What kind of criteria and guidelines would be most appropriate for evaluating papers reporting in-vitro studies on CHM? • How should the papers be selected for evaluation? • How should WP members organise for the pilot evaluation work? • What should be the guiding criteria in assessment of existing TCM databases and in-silico analytical tools? • What should be the main requirements of the website in order to use it as a common work platform for work package members? • When is the phase II kick-off meeting? • What should phase II kick-off meeting discuss?
D4.2: Kick-off meeting report: Agreed schedule of the task assignment of subgroups	<ul style="list-style-type: none"> • What are the main tasks in the report? • What are the main decisions taken during the WP4 kick off meeting? • What is the final list of WP4 tasks for the first twelve months? • What is the first draft list of suggested quality evaluation criteria, guidelines and tools for evaluating papers reporting in-vitro studies on CHM?
D4.3: Website building and maintenance	<ul style="list-style-type: none"> • Who should maintain the website? • What is the format for the website? • What content should be in the website? • How are the different pages linked? • What is the character of the website? • Should the website act as a forum for discussion? • Should this forum be private to WP4 members only? • Should it serve as an e-mail server? • Should this be a chat room? • Should the website send a message (like Skype) to say when visitors are on-line? • What structure, contents and features are needed for the WP4 web page? • Should contents be coordinated among WPs web pages, and how? • Should the web pages be accessible to every project member or some of them should be privilege restricted? • What topics should be covered for in-vitro TCM research for the website? • What would be the best type of electronic worksheet in order to allow different members to work on the same document or repository?
D4.4: Report of the discussion group on biological target oriented database	<ul style="list-style-type: none"> • Should there be a focus on certain disease areas? • If so, how should the areas be selected? • What analytical methods should be covered? • Should WP4 areas be identical into WP5 and WP6 areas or other WPs? • What are statistical methods used in the database? • What are the current trends in genomics, proteomics and pharmacogenomics, enzyme inhibition, receptor binding, genomics, proteomics, etc, etc?

	<ul style="list-style-type: none"> • What are the links of the database? • What are the fields of the database? • What is the principal application for a biological target oriented database? • What should be the main features for a pathology-oriented, comprehensive and quality scored repository on in-vitro pharmacological studies of CHM?
D4.5: Biological target oriented database for <i>in vitro</i> research on CHM	<ul style="list-style-type: none"> • What are the links of the database? • What are the fields of the database? • What should be the structure, using the pages of our web site, of a high quality, user-friendly repository for researchers on in-vitro pharmacology of CHM? • What areas, pathologies and biological targets will be covered initially? • What is the minimum number of papers that should be made available for each specific voice? • How will the repository merge with that of the other WPs? • What kind of search engine should be available for the repository? • How will the repository operate after the end of the project?
D4.6: Report on quality criteria and scoring of the CHM database	<ul style="list-style-type: none"> • What sections in articles should be reviewed? • How should the criteria be established? • Multiple reviews of a small number of articles by all members? • How to describe the criterion? • What is the relative importance of the criteria? • Has a general consensus been reached among the WP4 members on the scoring methodology and the evaluation criteria? • What is the final list of quality criteria, and how should they be properly applied to evaluate scientific papers on in-vitro research on CHM? • Can the selected criteria be applied to every kind of in-vitro research article on CHM without bias? • How can the methodology be validated?
D4.7: Update of CHM target oriented database with quality scores	<ul style="list-style-type: none"> • Which techniques should be considered for the quality scores? • What kinds of Chinese Herbal Medicines should be in the database? • How are the articles evaluated/ scored? • Is the proposed evaluation procedure suitable? • How should the evaluation scheme be modified, if necessary? • What number of scored papers can be considered adequate before the specific voice can be made available to the public? • How will the repository be updated, and by whom?
D4.8: Handbook on good practice in the reporting of CHM experimental work	<ul style="list-style-type: none"> • What kinds of in-vitro experimental work are usually done for the researches in the field of Chinese Herbal Medicines? • How to evaluate the experimental work listed in the Handbook? • What are the criteria for the evaluation of this experimental work? • Are the suggested criteria suitable and adequate for all suggestions? • What is the list of quality criteria, and how should they be properly applied to reporting of CHM experimental work? • What is the best didactic approach to provide guidance for best practice in future reporting of in-vitro data on CHM? • How should the good practice in the reporting of CHM experimental work be disseminated and made available to the scientific community?
D4.9: Discussion group evaluating data about molecular mechanisms of action of CHM	<ul style="list-style-type: none"> • How to narrow the range of the molecular mechanisms of action of CHM? • CHM has confirmed effects on what kinds of diseases in clinical studies? • These kinds of diseases have what molecular mechanisms? • Development of these molecular mechanisms?

	<ul style="list-style-type: none"> • What should be the specific criteria for evaluating scientific reports on CHM, suggestive of a link between the effect and a molecular mechanism of action? • What are the inclusion/exclusion criteria to be used for “molecular evidence”?
D4.10: Update of the CHM target oriented database with molecular mechanism evaluations	<ul style="list-style-type: none"> • What contents should be updated? • What type of changes should be made in the repository web pages in order to dedicate a sub-heading to papers on molecular mechanisms?
D4.11: Report on existing databases and software for <i>in silico</i> studies of phytocomplexes	<ul style="list-style-type: none"> • Which exiting database should be evaluated? • Which in-silico screening programme should be selected? • What is the state of the art of protein databases and software for in-silico studies? • Can the available software programmes for in-silico studies be readily applied to the study of phytocomplexes? • Can the available software be used effectively for target-oriented in-silico screening of bioactive materials from CHM?
D4.12: An interdisciplinary consensus meeting on <i>in silico</i> tools for CHM research	<ul style="list-style-type: none"> • What are the most software tools for in-silico screening? • What are the most appropriate targets for in-silico screening? • What scientific disciplines should be represented in the consensus meeting on in-silico tools for CHM research? • What are the issues on which the consensus on in-silico tools for CHM research should focus on? • What is the efficacy and applicability of in-silico tools to CHM research? • How can in-silico tools be best applied to CHM research? • What would be the specific software upgrades most needed for application to in-silico studies of phytocomplexes?
D4.13: Handbook of guidelines for using <i>in silico</i> tools in CHM research	<ul style="list-style-type: none"> • What is the most appropriate docking procedure (which software)? • What are the consensus guidelines for best practice in the application of in-silico studies to TCM research? • What is the best educational approach to provide guidance for best practice for in-silico studies in CHM research? • How should the consensus guidelines be disseminated and made available to the scientific community?
D4.14: Discussion group on use of functional genomic techniques for <i>in vitro</i> CHM research	<ul style="list-style-type: none"> • What kinds of functional genomic techniques are for in-vitro CHM research? • What is the most successful technique in lead discovery? • What are the main bottlenecks in the field of functional TCM in vitro research? • Can functional genomic techniques overcome basic problems in in-vitro research on phytocomplexes, and how? • To which extent are functional genomic techniques used among researchers in the CHM field? • What are the main obstacles for the use of a functional genomics approach by researchers in the CHM field? • Can functional genomics be used for the definition of protocols for early ADME methods in vitro and QSAR for ADME? (in conjunction with WP6)?
D4.15: Comprehensive report on the use of functional genomics in <i>in vitro</i> research of CHM	<ul style="list-style-type: none"> • What tasks and information are to be undertaken to produce a final report? • What are the technical, economical, analytical aspects of the use of functional genomics in in-vitro research of CHM? • Which special interest areas can be considered of critical importance for future developments of in-vitro research in TCM? • What is the best way to disseminate knowledge and foster a functional genomics approach within the in-vitro CHM scientific community?
<ul style="list-style-type: none"> • D4.16 Handbook for using functional 	<ul style="list-style-type: none"> • Fundamental questions: What is good practice for functional genomics in in-vitro research of CHM?

<p>genomics techniques in <i>in vitro</i> CHM research</p>	<ul style="list-style-type: none"> • What are the guidelines for functional genomics in in-vitro research of CHM? • What are the -omic analytical techniques that best apply to in vitro CHM research?
<ul style="list-style-type: none"> • D4.17 Report in the Final Conference 	<ul style="list-style-type: none"> • What is the format of the Final Conference? • What are the most meaningful suggestions and guidelines for best practice in the choice and application of functional genomics to TCM in-vitro research? • Can a functional genomics approach give a contribution to the standardization of in vitro research on TCM? • What is the best educational approach to provide guidance for best practice for in-silico studies in CHM research?
<ul style="list-style-type: none"> • D4.18 Submission of review papers for publication 	<ul style="list-style-type: none"> • Which journal is to be used for publication of papers according to the final report • Any additional questions need be addressed for the needs or publication?

5. WP5 –animal studies of CHMs

Deliverables	Central questions
D5.1 Kick-off meeting	Does anyone have questions about the GP-TCM project as a whole or in any details? Does everyone understand the vocabulary of importance to the whole project or specifically to this WP, for example the definition of CHM and functional genomics in this project? Does everyone understand the SOP for literature review? Does everyone understand D5.1-D5.15 are mandatory deliverables and have to be delivered on time and in high quality? If any mandatory deliverable are suggested to be modified, why? What are the long- and short-term objectives of the WP? What kind of a programme is needed for WP members to know each other better and to better discuss job assignment, long-term and short-term tasks?
D5.2 Website	What structure, contents and features are needed for the WP5 web page?
D5.3 Experts	What expertise do we have now? What do we need from additional experts?
D5.4 Review of literature relating to CHM in animal model and elaboration, circulation and discussion of the corresponding report. Report of the agreed conclusions	<p>In the preliminary report on the reviewed literature relating to CHM in animal models of disease, what do we wish to cover and explore? Current status of research, promises, problems, solutions, priorities?</p> <p>This question has already been answered, given that most central questions proposed by WP5 members and experts are focused on its CURRENT STATUS. Given that most WP5 members and experts have experience in cancer research, an in-depth review in cancer has been undertaken. It will be taken as a significant sample of the state-of-the-art in CHM studies in animals.</p> <p>What was the quality of the research from the perspective of a) modern medicine? b) Traditional Chinese Medicine?</p> <p>Based on the findings of the review in year one, what is controversial? What additional review is needed? Any areas of special importance? Why? What is agreeable within the WP?</p>
D5.5 Priority	Which areas are more mature and can be proposed for further studies? Which CHMs should be given priority for future research in CHM in animal models?
D5.6 Efficacy	Which CHMs have the most convincing efficacy in animal models? Why? What's the suggested future of these CHMs?
D5.7 Functional genomics	What's the current status of the application of functional genomics technology in animal studies, especially those focusing on CHMs? What are its strength and limitations in the context of all methods? Any recommendations on the application of functional genomics in the study of CHMs in animal models of disease? Why?
D5.8 "GP"	What good practice should be followed in animal studies of CHMs?
D5.9 Problems	What are the current problems in carrying out CMH studies in animal models?
D5.10 Priority	What future priority areas are recommended in animal studies of CHM? Why?
D5.11 Final meeting	What information is required and what tasks are to be undertaken to produce a report that can be discussed at the Final Conference and finally reported to EC?
D5.12 Publication	Which journal and which format are to be used for publication of paper(s) on the current status, challenges, solutions and priorities for animal studies of CHM products? Any additional questions need be addressed for publication purpose?

6. WP6- Clinical Studies of CHMs

Deliverables	Central questions and tasks
D6.1 WP kick-off Meeting	<ul style="list-style-type: none"> • How can we work together to deliver our tasks cooperatively? • What are the advantages and disadvantages of TCM for clinical studies as part of a complete healthcare system? • What topics are to be covered for TCM clinical research and trials by the group? • How are tasks allocated so that all agreed important topics are covered?
D6.2 Clinical expert network in TCM	<ul style="list-style-type: none"> • How many clinical experts should be invited and how to make our network function properly? • Should we invite more EU experts to join? • How to link effectively with our Chinese partners
D6.3 WP6 webpage	<ul style="list-style-type: none"> • What topics are covered for clinical TCM research and trials for the website? • How are tasks allocated so that all agreed topics are covered? • What is the format of the website: headings that can be used to assist coherent collation of relevant information? • What level of detail will be entered and how will we track ownership of data being gathered? • How to link with other aspects of the consortium's own website?
D6.4 Questionnaire	<ul style="list-style-type: none"> • How shall we design an international TCM questionnaire based on the key topics identified? • How are the survey's topics covered so that all agreed tasks are allocated? • How to collect, analyse data of the survey, and identify key finding and recommendations? • How do we coordinate information in association with WP8?
D6.5 Report on the review	<ul style="list-style-type: none"> • What key points will be included and in what format? • Do we link the report directly to the requirements of the ICH GCP? • What will be the target audience for this report?
D6.6 Review Conclusions	<ul style="list-style-type: none"> • What are the key conclusions and what tasks are needed to collate the literature review in an agreed format?
D6.7 Focus list of clinical areas and approaches to be supported written	<ul style="list-style-type: none"> • What are the best methodologies to meet the key questions and how can we improve current TCM research methodology? • How can the success of these approaches be used to reconcile TCM and Western approaches to disease and which diseases are most amenable to these approach? • How can we produce and disseminate TCM clinical guidelines (WHO guidelines or NICE guidelines?). • Other issues, such as ethics, safety and cost-effectiveness of TCM clinical trials.
D6.8 Functional genomics	<ul style="list-style-type: none"> • What specific genomic technologies can be employed in TCM research e.g. metabolomics for alterations in gut flora and metabolites? Predisposition and drug metabolism genes and pathways.
D6.9 Final Conference	<ul style="list-style-type: none"> • Presentation of the results of the survey • The clinical guidelines for TCM clinical trials.
D6.10 Final report published	<ul style="list-style-type: none"> • Which journals will be targeted for publication of papers on the survey on TCM: strengths and weaknesses

7. WP7- R&D and Market Entry Standards of CHMs

Deliverables	Central questions
D7.1 Kick-off Meeting	<ul style="list-style-type: none"> Where should the meeting be based? How many days are enough for such a meeting based on the budget and the programme? Does anyone have questions about the GP-TCM project as a whole or in any details? Does everyone understand the vocabulary of importance to the whole project or specifically to this WP, for example the definition of CHM (CMM) and functional genomics in this project? Does everyone understand the SOP for literature review? Does everyone understand deliverables D7.1-D7.8 are mandatory deliverables and have to be delivered on time and in high quality? If any mandatory deliverable are suggested to be modified, why? What are the long- and short-term objectives of the WP? What kind of a programme is needed for WP members to know each other better and to better discuss job assignment, long-term and short-term tasks? Any technical issues to be addressed?
D7.2 Web	<ul style="list-style-type: none"> Structure, contents and features are needed for the WP7 web page?
D7.3 Draft report	<ul style="list-style-type: none"> What are the regulatory systems for registration of CHM products (medicines /herbal supplements) existing among agencies (EMA, SFDA, FDA, TGA, NMPA in EU, China, USA, Australia and Canada respectively)? A catalogue of existing websites of the agencies on current requirements will be summarised for following up action. Changes will be monitored / updated over the 3-year period and concluded in the final report. What are the existing pharmacopoeia requirements for Chinese materia medica (CMM) that are used for development of CHM products among these agencies? Are there any problems in the existing official documents? How to establish a coordinating mechanism with WP1 on the specific pharmacopoeia standards stipulated by the agencies mentioned? What clinical studies and methodology are needed for registration of CHM products in the agencies mentioned? Outcomes from kick-off meeting may give some answers. Coordinating mechanism is needed with WP6 (Clinical studies). Are there any issues relating to CHM pharmaceutical medicines interactions? A coordinating mechanism is required with WP3 and WP6. A hyperlink can be utilised.
D7.4 Draft guidelines	<ul style="list-style-type: none"> What's the difference of D7.3, 7.4 and D7.5? Is it possible to make all these three important documents within the first year?
D7.5 Final guideline	<ul style="list-style-type: none"> Any additional questions need be answered after discussion of the draft guidelines?
D7.6 Functional genomics	<ul style="list-style-type: none"> What are the latest methodology & technology available for the quality control/assurance of CHM products? Outcomes from the kickoff meeting and literature search in conjunction with WP1 & WP2 will be needed. What functional genomics/other 'omics methodology and techniques have actually been used for R&D of CHM products? Outcomes from the kick-off meeting and review of literature on CHM products development for which 'omic' techniques have been applied can be summarised, correlated and coordinated with WP3 (toxicity), WP4 and WP5.
D7.7 Final Meeting	<ul style="list-style-type: none"> What information is required and what tasks are to be undertaken to produce a report that can be discussed at the Final Conference and finally reported to EC?
D7.8 Tel-meetings	<ul style="list-style-type: none"> What are the themes of these teleconferences? Any plan in advance?

8. WP8- Acupuncture

Deliverables	Central questions
D8.1 Kickoff meeting	<ul style="list-style-type: none"> ● Does every participant understand the objectives and the importance of the WP8-specific project? ● Does anyone have questions about the GP-TCM programme as a whole or in any details? ● Does everyone understand the mandatory deliverables and does any of the mandatory deliverables are suggested to be modified (based on generally acceptable reasons)? ● Do any of the long- and short-term objectives of the WP (included in the 3-year plan) need to be justified? Why and how? ● How can we improve the involvement of and collaboration between both the Chinese and EU members of the WP? ● What would be the best way to liaison with WP6 and deliver the survey on time and in good quantity.
D8.2 Webpage	<ul style="list-style-type: none"> ● What style or format can be selected for the site? ● What categories can be considered to be incorporated for the WP webpage? ● Any external links can be used to acquire data in different websites? ● How to encourage and manage the contribution from the WP members for the webpage construction? ● How are tasks allocated so that all agreed topics are covered ● Does anyone need assistance or training for the access of the WP webpage?
D8.3 Survey	<ul style="list-style-type: none"> ● How shall we design an international questionnaire based on the key topics identified? ● How are the survey's topics covered so that all agreed tasks are allocated? ● How to collect, analyse data of the survey, and identify key finding and recommendations? ● How do we coordinate the operation and share information in association with WP6?
D8.4 Teleconferences	<ul style="list-style-type: none"> ● What are the themes and arrangements of the teleconferences? ● Any concerns with the web-based teleconferencing to be encouraged as the primary communication method? ● How can we improve the communication with the WP8 EU members? ● Whether the EU members need to be organised and contacted through a subgroup leader? ● What is the approach for the non-WP lead members to request and arrange for group discussions via teleconferencing?
D8.5 Primary report on functional genomic studies of acupuncture	<ul style="list-style-type: none"> ● What are the potential key conclusions or achievements from the WP8 project? ● What are the best suggestions that WP8 can make for the EC to setup further collaborative studies in acupuncture/moxibustion-related researches? ● What can be the monumental or representative reports in EU and in China in acupuncture studies based on the literature review? ● What can be summarised from the current status and challenges in acupuncture researches/clinics in EU and China? What are in common and what are the major differences? (can be in specific aspects) ● Any related patent or industrial product needs to be paid attention? ● How can we better include the information from the studies in other eastern or western countries besides China and EU?
D8.6 Final conference	<ul style="list-style-type: none"> ● Whether to conjointly or individually present the survey results? ● How to produce a report with a representative and generally accepted overview of functional genomics in studies of acupuncture and moxibustion from both the EU and Chinese of views?
D8.7 Final report	<ul style="list-style-type: none"> ● What is required and what tasks are to be carried out to file the report to be discussed at the Final Conference?

D8.8 Publication	<ul style="list-style-type: none">● Which format or journal will be suitable for the publication of paper(s) based on the analyses of the current status and progress on the studies of WP focuses?● Any additional questions or concerns need be addressed for publication purpose?● Are there any selected articles/documents considered worthwhile for the translation from Chinese to English, or vice versa?● Does WP8 need or have we got sufficient support for editorial assistance?
---------------------	---