

## Newsletter

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## US Agencies Publish Draft Streamlined Clinical Trial Protocol Template to Help Investigators

The United States' National National Institutes of Health ("NIH") and US Food and Drug Administration ("FDA") have published a draft protocol template with the aim of increasing the efficiency of clinical trial protocol reviews.

The draft protocol was developed to help investigators in preparing protocols that comply with the ICH E6 Good Clinical Practice guidance. It serves as a suggested format for NIH-funded Phase II and III clinical trials done in support of an investigational new drug application or investigational device exemption.

The public consultation for the draft protocol template took place from 17 March 2016 to 17 April 2016. The draft protocol template can be found on the NIH's website [here](#).

## Singapore's Import Declaration Requirements for Health Products to Change From 3 May 2016

The Singapore Health Sciences Authority ("HSA") has announced key changes to import declaration requirements for health products, which will take effect on 3 May 2016. The changes are as follows:

- Having one single Competent Authority for all health products, so that all categories of health products can be declared within the same TradeNet® permit application;
- Removing the need to declare HSA Product Codes for health products not currently subject to licensing / approval requirements, such as cosmetic products, health supplements, quasi-medicines, traditional medicines, medicated oils and balms, herbal materials and homeopathic medicines; and
- Simplifying HSA Product Codes to be used for 5 categories of regulated health products.

Details of the HSA circular can be found on the HSA's website [here](#).

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## NHG Challenges Health Innovation With Games

Singapore's National Healthcare Group ("**NHG**") officially launched the inaugural Health Innovation Technology ("**HIT**") Challenge on 28 March 2016 in collaboration with the Infocomm Development Authority of Singapore ("**IDA**") and the Serious Games Association ("**SGA**").

The objective of the HIT Challenge is to encourage healthcare staff across Singapore to work with gaming developers to create applications and games to help patients and staff better understand illnesses.

A Memorandum of Intent was also signed between NHG, IDA and SGA, to pledge their commitment to further the integration of gaming technology within Singapore's healthcare sector.

For more information, please refer to the HIT Challenge's website [here](#).

## HSA Allows Sale and Import of Berberine-containing Chinese Herbs

The Singapore Health Sciences Authority ("**HSA**") has lifted the ban on Chinese herbs containing berberine, allowing Traditional Chinese Medicine ("**TCM**") practitioners to import and sell the herbs from 1 April 2016.

The HSA does not regulate the import and sale of Chinese herbs for TCM use and the onus is on the dealer to ensure that those herbs do not contain any prohibited substances or toxic heavy metals above permissible limits.

Chinese Proprietary Medicines continue to be regulated, and dealers of Chinese Proprietary Medicines containing berberine will still be subject to pre-market approval and licensing with the HSA.

For more information, please refer to HSA's press release [here](#).

## Overseas Alert Triggers Food Recall in Singapore

Following an alert issued by Food Standards Australia New Zealand, the Agri-Food And Veterinary Association of Singapore ("**AVA**") confirmed that selected batches of Spring Bay Australian Mussels have been recalled due to a biotoxin contamination.

The AVA has the power to order a mandatory recall of the product, and may do so as a precautionary measure if the same product is being recalled by the local authorities or the product owner in another jurisdiction. Such recalls may also be voluntarily conducted by the importer.

For more information, please refer to AVA's press release [here](#).