

# AHCC Trials Group

Newsletter Apr 2014

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## AHCC Trials Group

### Group Chair:

Prof Soo Khee Chee

### Protocol Chair, AHCC06:

Prof Pierce Chow

### Trials Group Website:

<http://www.scri.edu.sg/index.php/ahcc-trials-group>

### Trial Coordinating Centre:

## The Buzz

### AHCC06 receives additional funding of up to SGD 1.9 million

*AHCC06: Phase III Multi-Centre Open - Label Randomized Controlled Trial of Selective Internal Radiation Therapy (SIRT) Versus Sorafenib in Locally Advanced Hepatocellular Carcinoma (SIRveNIB)*

#### Greetings to all members of the AHCC Trials Group!

It is with great pleasure that we inform you that the AHCC Trials Group has been awarded additional funding of up to SGD 1.9 million from Sirtex for the AHCC06 trial. The AHCC06 trial is the largest trial to date conducted by the AHCC Trials Group and is supported by the National Medical Research Council (NMRC) and Sirtex Medical with a combined funding of more than SGD 10 million.

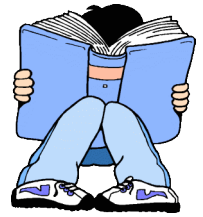
The request for additional funding to Sirtex followed the 2<sup>nd</sup> AHCC06 Investigators Meeting in Singapore on 16<sup>th</sup> November 2012 where the need was raised by investigators. The feedback was taken seriously and much work was done to assess the issue and a proposal for the additional funding was submitted to Sirtex. The contract awarding the additional funding was signed by Sirtex on the 8<sup>th</sup> February 2014. SCRI is currently finalising payment schedule amendments to enable this money to be made available to the sites, and will be circulating the amendment to sites shortly.

This is indeed good news for the AHCC06 trial - the additional funding is designated for supporting study-related and follow-up measures, such as enabling current and future patients to have their tests and investigations done without out-of-pocket cost to them until study conclusion. These will also improve the overall study data quality and recruitment rate.

The extra funding is a positive development for the AHCC06 trial as it represents confidence in the trial and encourages the study team. We would like to thank Sirtex, the study teams from all the sites and all the study teams in SCRI and SGH for their valuable and significant contribution to the study.

## Published:

We are very happy to share our latest publication of the AHCC05 trial, titled **“Multicentre Phase II study of Sequential Radioembolization-Sorafenib Therapy for Inoperable Hepatocellular Carcinoma”** with PLOS ONE. The publication is open access and available online at: <http://dx.plos.org/10.1371/journal.pone.0090909>.



Chow PKH, Poon DYH, Khin MW, Han HS, Goh ASW, Choo SP, Lai HK, Lo RHG, Tay KH, Lim TG, Gandhi M, Tan SB, Soo KC. *Multicenter Phase II Study of Sequential Radioembolization-Sorafenib Therapy for Inoperable Hepatocellular Carcinoma*. *PLoS One*, 2014. 9(3):p.e90909.

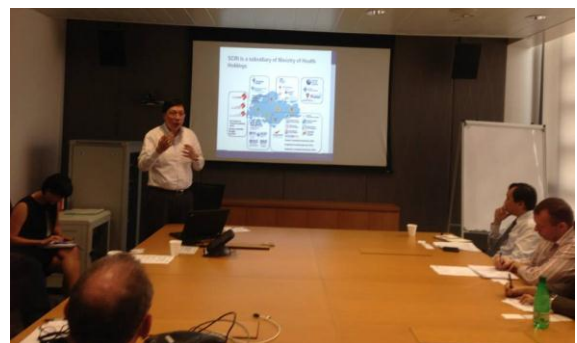
## AHCC Trials Group’s Proposal on Collaborative Partnership

From its establishment in 1997, the AHCC Trials Group has been a network of leading clinicians and key opinion leaders from the Asia-Pacific with the common aim of carrying out definitive multi-centre trials and other research on HCC in the Asia-Pacific, a region where the disease is endemic. To date, the Trials Group has successfully launched six multi-centre prospective clinical trials on HCC that has involved more than 30 participating centres from 18 countries in the region.

The strength of the AHCC Trials Group lies in its spread of collaborating centres and its track record of successfully completed trials. These enable the trials conducted within the network to tap on a large number of eligible patients. Not only does the AHCC Trials Group allow more patients access to treatment, it also facilitate completion of clinical trials in a more timely manner.

The Trials Group has reached a stage in its development where it is mutually meaningful for our established network is to develop a collaborative platform with external research parties both regionally and internationally. In order to move this strategic initiative forward, Prof Pierce Chow, Protocol Chair of AHCC06, Dr Teoh Yee Leong, CEO of SCRI, and Dr Guy Heathers, Director of Technology Development, National Cancer Centre Singapore presented a collaborative partnership proposal at Duke-NUS Graduate Medical School on the 20<sup>th</sup> February 2014. The audience included pharmaceutical companies and clinical research organisations. The proposal was well –received and discussions with several interested parties are underway.

All of this would not have been possible without the support of everyone involved.



Prof Chow (Protocol Chair, AHCC06) and Dr Teoh (CEO, SCRI) at the presentation.

## AHCC06 (SIRveNIB)

### Phase III Multi-Centre Open-Label Randomized Control Trial of Selective Internal Radiation Therapy (SIRT) Versus Sorafenib in Locally Advanced Hepatocellular Carcinoma

Protocol Chair: Prof Pierce Chow, NCCS, SGH and Duke-NUS

#### Study Status:

As of 31<sup>st</sup> March 2014, the total number of patients recruited is 242 with Myanmar and Mongolia having the highest recruitment numbers. The trial is at 67% of the target recruitment of 360.

The trial has progressed well and the news of the additional funding is celebrated by the study team and sites. The last Investigators' Meeting was fruitful with critical feedback addressed and new ancillary studies developed. The next Investigators' Meeting is planned to be in July in conjunction with APPLE 2014 in Taipei, Taiwan.

The trial is also due for its second Interim Analysis soon, estimated to occur before end of 2014. The first Interim Analysis held on 22<sup>nd</sup> May 2013 affirmed the trials to be on track with no safety concerns. The second interim analysis aims to review safety and efficacy.

Given the progress to date, the AHCC06 study team looks forward to an exciting and fruitful 2014.

For more details on the AHCC06 trials, please visit <http://www.sirvenib.com/>

#### Participating Centres:

##### Brunei

- The Brunei Cancer Centre

##### Hong Kong

- Queen Mary Hospital

##### Indonesia

- University of Indonesia
- Sanglah General Hospital

##### Korea

- Asan Medical Center
- Korea Anam University Hospital
- Seoul National University Bundang Hospital
- Seoul St. Mary's Hospital
- Severance Hospital

##### Malaysia

- Penang Adventist Hospital

##### Mongolia

- National Cancer Center

##### Myanmar

- Yangon GI & Liver Centre

##### New Zealand

- Auckland City Hospital

##### Philippines

- Makati Medical Center
- St. Luke's Medical Center
- The Medical City
- Davao Doctors Hospital

##### Singapore

- Khoo Teck Puat Hospital
- National Cancer Centre
- National University Hospital
- Singapore General Hospital

##### Taiwan

- National Taiwan University Hospital
- Chang Gung Memorial Hospital, LK
- Taipei Veterans General Hospital
- China Medical University Hospital

##### Thailand

- Chulabhorn Hospital



Investigators enjoying a drink following the Taiwan Investigators' Meeting in Taipei, Taiwan.



## Sarawak General Hospital, AHCC06 Site Qualification Visit, 31 Oct 2013

Prof Chow and the SCRI team visited Sarawak General Hospital for a site qualification visit. The study team was impressed by the multi-disciplinary teamwork at the hospital. We look forward to fostering a close working relationship with Sarawak General Hospital.

Site PI: Dr James Law



*Prof Chow and the study team at Sarawak General Hospital*

## AHCC06 Taiwan Investigators' Meeting, 15 Feb 2014

The Taiwan Investigators' meeting was attended by representatives from TVGH, CGMH-LK, NTUH, CMUH, Choice Pharma and Synmosa. The meeting covers updates on the trial and each site presented the challenges at the site. Many queries were clarified. It was a successful meeting and sites were excited about the additional funding from Sirtex. They are optimistic that the additional funding will improve the quality of the trial.

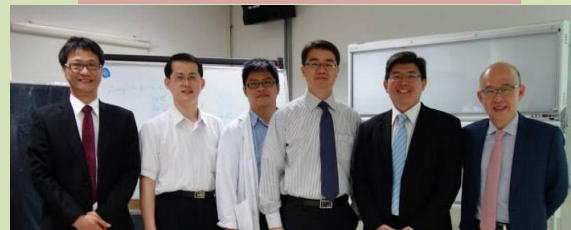


*Prof Chow and Ms Sophie Moss (Project Manager) with the study team in Taiwan*

## China Medical University Hospital, AHCC06 Site Initiation Visit, 3 Apr 2014

The site was initiated by Prof Pierce Chow, Protocol Chair of AHCC06 and Dr Wong, steering committee member of AHCC06 conducted the SIV. Both also made a trip to National Cheng Kung University Hospital, NCKUH for a site evaluation visit.

Site PI: Prof Peng Cheng Yuan



*Prof Chow and Dr Wong conducting the SIV at China Medical University Hospital*

## Contact Details

For further queries, please contact the AHCC Trials Group at



Project Manager (AHCC06):  
**Ms Sophie Elizabeth Moss**  
Email: [sophie.moss@scri.edu.sg](mailto:sophie.moss@scri.edu.sg)  
DID: (65) 6508 8314



Network Secretariat:  
**Ms Lynette Lai**  
Email: [lynette.lai.s.h@sqh.com.sg](mailto:lynette.lai.s.h@sqh.com.sg)  
DID: (65) 6576 2151

Mailing Address: 31 Biopolis Way Nanos #02-01 Singapore 138669

Read more about all trials  
under AHCC Trials Group at  
<http://www.scri.edu.sg>.

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