Celebrating 20 Years of Clinical Research with Our Partners

IN SEARCH OF BETTER TREATMENTS FOR OUR PATIENTS

ANNUAL REPORT 2016/2017
As the national academic clinical research organisation, SCRI is dedicated to enhancing the standards of clinical research capabilities in Singapore. SCRI leads in scientific collaboration and research innovation to search with our healthcare partners for better treatment outcomes for patients. Together, the nation is set to develop core capabilities and thought leadership for clinical research excellence.

With robust coordination abilities and infrastructure, SCRI is ready to advance Singapore in the field of clinical research for the coming years.
The Singapore Clinical Research Institute (SCRI), a wholly-owned subsidiary of the Ministry of Health Holdings (MOHH), has 20 years of experience in managing clinical research activities. Its predecessor was the Clinical Trials and Epidemiology Research Unit (CTERU) established by the Ministry of Health in November 1996.

20 years ago, clinical research was a new catchphrase, what some considered as a leap of faith, or a label to categorise existing research of similar nature.

Yet, the founders of CTERU were visionaries who understood that we could become a preferred site for executing clinical trials in Asia, in addition to planning and coordinating investigator-led, multi-national clinical trials.
Funded by the National Medical Research Council (NMRC), the mission of CTERU was to provide infrastructure support for public-sector clinical research and evidence-based medicine. In line with this directive, CTERU carried out multi-centre clinical trials, epidemiological and systematic reviews as well as training in the core skills of evidence-based medicine pegged at international standards.

In September 2008, CTERU was restructured as SCRI, a national academic clinical research institute. Building upon CTERU’s foundations and dedicated to enhancing the standards of clinical research, SCRI strives to develop core capabilities and scientific leadership in Singapore. The organisation focuses on providing technical expertise, organisation, processes and Information Technology system excellence to support collaborative clinical research.

The growth of SCRI has also seen it breaking new ground in establishing clinical research networks and conducting innovative research methodology courses.

It has been a journey fraught with reservations and yet hope, with SCRI proving that clinical research can make a difference towards a better future for Singapore. From liver cancer to myopia, diabetes to dengue, we are on a voyage of translating science into cures, giving hope to patients and their families.

Today, SCRI’s collaborative platform matches the right researchers to significant healthcare problems, bringing therapies to a multi-ethnic population in Asia. Handling challenges with grace, carving a pathway for the future of healthcare and research talents as well as bringing the region’s healthcare practitioners together, SCRI has come a long way from its beginnings as CTERU. Our 20 years of growth will continue to guide us and our partners in search of even better treatments for our patients.

Clinical research has become an important pursuit and national asset for Singapore today. SCRI is testament to this common purpose, and will continue to support researchers in finding the best answers for the future of global health.

From left to right: SCRI Chairman, Associate Professor John Lim; Senior Minister of State, Ministry of Communications and Information & Ministry of Health, Mr Chee Hong Tat; SCRI CEO, Associate Professor Teoh Yee Leong.

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From left to right: SCRI Chairman, Associate Professor John Lim; Senior Minister of State, Ministry of Communications and Information & Ministry of Health, Mr Chee Hong Tat; SCRI CEO, Associate Professor Teoh Yee Leong.
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As the national academic research organisation within the Ministry of Health Holdings family, SCRI plays a crucial role today in enhancing the efficiencies of clinical trials headed by Singapore’s clinician investigators within our shores and beyond.

Associate Professor John Lim
Chairman, SCRI
It has been twenty years since the Singapore Clinical Research Institute’s predecessor, the Clinical Trials and Epidemiology Unit (CTERU), was established as a unit of the Ministry of Health (MOH) to encourage and support physicians conducting scientific research in Singapore’s public sector healthcare institutions.

The clinical research journey since then has been exciting and fruitful. SCRI continues to honour and enthusiastically embrace its original role, but has also expanded in scope to strengthen wider aspects of the clinical research ecosystem in Singapore and the region.

**EMBRACING OUR NEW ROLES**

As the academic research organisation within the MOH Holdings family, SCRI plays a crucial national role in enabling and enhancing clinical trials spearheaded by Singapore’s public sector clinicians, both within and beyond our shores. The organisation’s vision is to become an ASEAN hub of academically oriented clinical research initiatives.

SCRI is well placed to support our healthcare professionals and institutions because of the breadth of our strong partnerships around the region and the depth of established internal expertise. We work with pharmaceutical, healthcare and medical research partners to actively enhance Singapore’s clinical research infrastructure, and seek continuous improvement of clinical care for our patients.

SCRI is presently developing a joint national training programme and structuring clear career pathways for Clinical Research Coordinators with our key public sector healthcare partners. In doing so, SCRI is moving beyond providing essential support for clinical studies to address some critical enabling issues for the local research scene. These advances will also provide momentum in improving research capabilities at the national level, and further support industry-funded clinical trials. In the national role of facilitating clinical research efficiency in Singapore, SCRI also supports the research offices of our public healthcare institutions in helping them track their respective clinical trial project milestones and providing legal input to facilitate clinical trial agreements between institutions and trial sponsors.
THE NEXT CHAPTER
SCRI continually conducts horizon scanning to ensure it maintains its relevance for cutting edge clinical research and new areas that are of relevance and appropriate to Singapore. For example, there is a need to look beyond the conventional models of clinical research and aim to support new models of clinical trials, such as adaptive trial designs and the use of big data and real world evidence.

Building on the strengths of its epidemiological, biostatistical and clinical monitoring expertise, SCRI can also assist investigators to consider wider aspects of the R&D continuum, including regulatory and commercialisation issues when designing clinical development plans. The incorporation of the National Health Innovation Centre as a business unit of SCRI will facilitate this. In addition, to match the evolving research and economic landscape of Singapore, SCRI’s support will also extend to local medical technology and device trials.

In light of these new areas, SCRI will always have to ensure that its relatively small team of highly professional and expert scientific staff comprises the right mix of skill sets. They will also engage and support the next generation of clinical investigators in our public sector institutions.

SCRI is indeed fortunate to have a strong and committed team of scientific professionals with the vision for a continuing trajectory of growth that builds on the strong foundation laid by their predecessors. The successes of today are possible because of the efforts of CTERU’s pioneers who strongly believed in the mission of establishing an academic research organisation for the country. SCRI’s robust and ongoing development is testament to their vision and dedication.

WITH GRATITUDE
On behalf of the Board of Directors, I would like to express my appreciation for the continuous support of the Ministry of Health, the National Medical Research Council, and our public sector healthcare clusters who have steadfastly worked with and partnered CTERU and SCRI over the years.

We are also very grateful for the sound leadership of SCRI’s CEO, Associate Professor Teoh Yee Leong, who together with his senior management team and all the Institute’s extremely committed and professional staff continue to write the next exciting chapters of the SCRI story.
2016 was a special year for us as we celebrated our 20th year of spearheading clinical research in Singapore, first as the Clinical Trials and Epidemiology Research Unit (CTERU) and now as SCRI.

**EXPANDED CAPABILITIES AND OPERATIONS**

Over the past two decades, our organisation’s scope of capabilities and operations has grown. Today, SCRI offers not only epidemiology and biostatistics support in clinical research, but also support in the areas of cost-effectiveness studies, clinical trial operations and logistics, including project management, data management, research monitoring and research informatics.

We also work to facilitate clinical trial efficiency across the country, and are running more multi-centred, investigator-led studies outside of Singapore than ever before in collaboration with our strong network of overseas research partners.

SCRI will also continue to be involved in the growing number of investigator-initiated trials by providing comprehensive support to investigators, from the grant application process to protocol design and data management to publication.

Associate Professor Teoh Yee Leong
CEO, SCRI
KEY ACHIEVEMENTS IN 2016
2016 was a fruitful year for us as we continued to work with our patients in both the public and private sectors to break new ground.

Significantly, we completed recruitment of the Asia-Pacific Hepatocellular Carcinoma (AHCC) 06 trial, one of our flagship studies comparing the outcomes of two established treatments in patients with locally-advanced hepatocellular carcinoma.

It is worthwhile to note that AHCC06 is a study stemming from the AHCC Trials Group set up by CTERU during the beginnings of the institute. The results of the AHCC06 study will be presented at the 2017 American Society of Clinical Oncology Annual Meeting.

In addition, together with the National Cancer Centre Singapore (NCCS) and our commercial partner IMS Health Asia Pte Ltd, we set up the Hepatocellular Carcinoma (liver cancer) Registry in Asia. The registry is the first of its kind in Asia and seeks to collate data that answers important questions on the management of liver cancer patients, which would be relevant to policymakers and healthcare professionals in formulating the appropriate strategies for patient care.

We also continued our mission to improve the efficiency of local clinical research operations. To this end, we began the planning of a joint national training programme for Clinical Research Coordinators (CRCs) which seeks to improve the technical competency and career structure of our coordinators. Among other benefits, the programme will provide core-funding for 100 CRCs, as well as on-the-job training for new graduates who are interested in pursuing the CRC path. It is expected that the first phase of the programme will be rolled out in mid-2017.

LOOKING FORWARD
There is yet more to look forward to in the coming year. Having successfully completed our studies on ATOM1 and ATOM2, which showed that Atropine, even at a low dose, was successful in slowing the progression of myopia, we are working with the Singapore National Eye Centre (SNEC) and Singapore Eye Research Institute (SERI) to study if low dose Atropine can be used to prevent the onset of myopia (ATOM3 study). The research is of significant public health interest given the high rate of myopia among children in Singapore.

SCRI will also continue to be involved in the growing number of investigator-initiated trials by providing comprehensive support to investigators, from the grant application process to protocol design and data management to publication. Our foreign partnerships are particularly important in this respect as many of these trials will involve overseas sites.

IN APPRECIATION
In closing, I would like to express my gratitude to our Chairman and Board of Directors for their direction and continued support. To our staff, a big thank you for your hard work and dedication as we continue to do our part for the clinical research scene in Singapore and across the region. I look forward to what we are going to achieve together in the coming year.

We also work to facilitate clinical trial efficiency across the country, and are running more multi-centred, investigator-led studies outside of Singapore than ever before in collaboration with our strong network of overseas research partners.
VISION
To be the ASEAN hub of academically-oriented clinical research efforts

MISSION
To spearhead and develop core capabilities, infrastructure and scientific leadership for clinical research in Singapore

CORE VALUES

SCIENTIFIC
We believe in clinical research in accordance to the scientific method

COLLABORATIVE
We believe in collaborating closely with partners in clinical research

RELIABLE
We believe in providing reliable support for our clinical research work

INNOVATIVE
We believe in being innovative in clinical research work
BOARD OF DIRECTORS

ASSOCIATE PROFESSOR JOHN LIM (CHAIRMAN)
Deputy Director of Medical Services
(Industry & Research Matters)
Ministry of Health (MOH)

Executive Director
Centre of Regulatory Excellence
Duke-NUS Medical School Singapore

PROFESSOR SOO KHEE CHEE
Director
National Cancer Centre Singapore (NCCS)

Deputy Group Chief Executive Officer
Research and Education
Singapore Health Services (SingHealth)

Senior Vice Dean
Clinical, Academic and Faculty Affairs
Duke-NUS Medical School Singapore

TRICIA HUANG
Executive Director
National Medical Research Council
Ministry of Health (MOH)

ASSOCIATE PROFESSOR TAN SAY BENG
Group Director, Research
Singapore Health Services (SingHealth)

Senior Associate Dean
Office of Clinical Sciences
Duke-NUS Medical School Singapore
ASSOCIATE PROFESSOR LYNETTE SHEK PEI-CHI
Vice Chairman
Medical Board (Research)
Head and Senior Consultant
(Division of Paediatric Allergy, Immunology and Rheumatology)
National University Hospital (NUH)

ADJUNCT ASSOCIATE PROFESSOR GOH BOON CHER
Head/Senior Consultant
Department of Haematology-Oncology
National University Cancer Institute Singapore (NCIS)
Director
Investigational Medicine Unit
National University Health System (NUHS)
Deputy Director
Cancer Science Institute of Singapore
National University of Singapore (NUS)
Adjunct Associate Professor
Department of Pharmacology
National University of Singapore (NUS)
Adjunct Senior Research Scientist
Defence Medical and Epidemiology Research Institute, Singapore

VIJAYALETCHIMI D/O EGAMPARAM
Director, Finance
MOH Holdings Pte Ltd (MOHH)

ADJUNCT PROFESSOR LIM TOCK HAN
Deputy Group CEO
(Education & Research)
National Healthcare Group Pte Ltd (NHG)
Senior Consultant
National Healthcare Group Eye Institute
Tan Tock Seng Hospital (TTSH)

PROFESSOR JOSEPH YEONG WEE YONG
Chairman
Sing Investments & Finance Limited

HO WENGI
Director
Biomedical Sciences
Economic Development Board (EDB)

As of 31 December 2016
SENIOR MANAGEMENT

1: Associate Professor Teoh Yee Leong
Chief Executive Officer

2: Dr Gao Hong
Head, Project Management & Pharmacovigilance

3: Damien Hong
Chief Operating Officer

4: Peter Tan
Head, Human Resources & Talent Development

5: Dr Shi Luming
Head, Epidemiology

6: Au Wing Hong
Head, Finance

7: Janice Ng
Head, Research Monitoring

8: Lisa Tan
Head, Corporate Affairs

9: Huang Kuanfu
Head, Research Informatics

10: Mihir Gandhi
Head, Biostatistics

11: Associate Professor Edwin Chan
Chief Scientific Officer

12: Ng Xuanhui
Head, Data Management

As of 31 March 2017
SCRI PARTNERSHIP WITH INVESTIGATORS ROADMAP

1. SCIENTIFIC & CLINICAL PARTNERSHIP
2. STUDY FEASIBILITY ASSESSMENT
3. PROTOCOL DEVELOPMENT
4. ETHICS SUBMISSION
5. STUDY BUDGETING
6. PROJECT MANAGEMENT
7. RESEARCH DATABASE
8. ADVERSE EVENT REPORTING
SCREENING & RECRUITMENT, IP ADMISSION, DATA ENTRY AND LABORATORY MANAGEMENT AT STUDY SITE

RESEARCH MONITORING

DATA MANAGEMENT

BIO-STATISTICAL ANALYSIS

PUBLICATION

STUDY SITE DOCUMENT ARCHIVING

STUDY COMPLETE

IN SEARCH OF BETTER TREATMENTS FOR OUR PATIENTS
SCRI works with its healthcare partners on clinical trials that meet international standards on a range of therapeutic areas with special focus on diseases of Asian significance.
KEY FACTS AND FIGURES

135,877 Research Subjects Enrolled for Research Studies*

*All research studies with patients involving SCRI.

8,654 Human Subjects Enrolled in Clinical Trials

No. of patients enrolled in:
- Clinical Trials
- All Research Studies

Clinical Research Studies (2014-2016)

Scientific and Operational Team in 2016

A diversified team of 57

Scientific and Operational Staff
Achievements Since SCRI’s Incorporation in 2008

- Worked with 736 Investigators
- Supported 216 Local and International Sites across 25 Countries
- Research Findings published in 246 Publications
- Conducted and Participated in 186 Workshops, Seminars & Conferences
- Conducted 137 Studies

Data on file
## FUNDING SOURCES AND COLLABORATORS

<table>
<thead>
<tr>
<th>SOURCE</th>
<th>KEY COLLABORATORS IN FY2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>NMRC</td>
<td>Alexandra Health Pte Ltd&lt;br&gt;Duke-NUS Medical School&lt;br&gt;Tan Tock Seng Hospital Pte Ltd&lt;br&gt;Singapore General Hospital Pte Ltd&lt;br&gt;National University of Singapore&lt;br&gt;National University Hospital (S) Pte Ltd&lt;br&gt;Singapore Eye Research Institute&lt;br&gt;KK Women's and Children's Hospital Pte Ltd&lt;br&gt;National Cancer Centre&lt;br&gt;Changi General Hospital Pte Ltd&lt;br&gt;Asia Cornea Foundation&lt;br&gt;Institute of Mental Health&lt;br&gt;National Heart Centre of Singapore Pte Ltd</td>
</tr>
<tr>
<td>COMMERCIAL</td>
<td>Danone Baby Nutrition&lt;br&gt;Merck Pte Ltd&lt;br&gt;MicroVax LLC&lt;br&gt;IMS Health Asia Pte Ltd&lt;br&gt;Innogene Kalbiotech Pte Ltd&lt;br&gt;SIRTEX Technology Pty Ltd</td>
</tr>
<tr>
<td>FOUNDATION</td>
<td>Viva Foundation&lt;br&gt;Asia Cornea Foundation&lt;br&gt;Tanoto Foundation&lt;br&gt;International Myeloma Foundation</td>
</tr>
<tr>
<td>INDEPENDENT</td>
<td>National University of Singapore&lt;br&gt;Singapore General Hospital Pte Ltd&lt;br&gt;Duke-NUS Medical School&lt;br&gt;Perinatal Society of Singapore&lt;br&gt;KK Women's and Children's Hospital Pte Ltd&lt;br&gt;D3 (Drug Discovery and Development)</td>
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### COMMERCIAL
- **S$256,997.84**

### INDEPENDENT
- **S$263,709.84**

### FOUNDATION
- **S$280,052.31**

### NMRC TRIALS
- **S$1,020,551.39**

### NMRC CORE GRANT
- **S$7,637,153.45**

### FY 2016 GRAND TOTAL
- **S$9,458,464.83**
THERAPEUTIC AREAS

INFECTION DISEASE
We remain vulnerable to infectious diseases like dengue with more than 10,000 cases reported in 2016.

PSYCHIATRY
The Singapore Mental Health Study 2010 found that about one in 10 people in Singapore suffer from a mental disorder.

CARDIOLOGY
Every day, 16 people in Singapore die from cardiovascular disease and its complications (heart disease and stroke).

EMERGENCY MEDICINE
2016 saw more than 1 million emergency attendances in Singapore’s public hospitals.

PAEDIATRICS
More than 33,000 Singaporean babies were born in 2016.

ONCOLOGY
Cancer is the number one cause of death in Singapore, and research into cancer prevention and treatment is a national priority.

OPHTHALMOLOGY
Eye diseases are common among our population, one of which is childhood myopia which affects two out of three 12-year-olds in Singapore.

NEUROLOGY
1 in 10 stroke patients in Singapore is under age 50.

ENDOCRINOLOGY
Diabetes is one of the fastest growing chronic diseases in Singapore; its prevalence in the population has increased from 8.6% in 1992 to 11.3% in 2010.

OTHERS
Anaesthesiology, Dietetics, Gastroenterology, Gynaecology, Haematology, Head and Neck, Medical Device, Musculoskeletal, Neonatology, Nephrology, Nutrition, Orthopaedics, Psychology, Quality of Life, Respiratory, Rheumatology, Statistical, Surgery, Vascular

Source:
KEY PROJECTS IN 2016

AHCC REGISTRY

AHCC Registry is led by Professor Pierce Chow from the National Cancer Centre Singapore (NCCS). A first in Asia, this is an investigator-initiated registry established with the aim to provide a complete longitudinal picture of the hepatocellular carcinoma patient journey in several representative Asian countries. NCCS, the Asia-Pacific Hepatocellular Carcinoma Trials Group Network and SCRI are partnering QuintilesIMS for the development of the registry.

ATOM3

Led by both Professor Donald Tan and Associate Professor Audrey Chia of the Singapore Eye Research Institute (SERI), ATOM3 is based on previous ATOM trials and epidemiological studies to investigate the use of low-dose Atropine in myopia prevention and control in a younger population. The study is funded by NMRC and Asia Cornea Foundation (ACF). SCRI supports the study through project management, site initiation and monitoring, pharmacovigilance, data analysis and management.

ASCOLT

Led by Dr John Chia from the NCCS, ASCOLT is a study which investigates the role of aspirin in the treatment of colon cancer. This study has funding from philanthropic organisations such as the Swiss Rising Tide Foundation and involves more than 35 global sites. The study is currently on-going with SCRI supporting its overseas operations.

ARV7

Dr Ravindran Kanesvaran of NCCS leads the ARV7 collaboration which aims to determine the prevalence and incidence of the AR-V7 splice variant in an Asian population of patients with Castration-Resistant Prostate Cancer (CRPC). The study focuses on the effect of the AR-V7 variant on the Asian population and how different treatments impact the patient outcomes in this group of patients.

The study is co-funded by the pharmaceutical company Sanofi and National Medical Research Council (NMRC), and is now conducted in eight sites within key hospitals in five countries. SCRI supports the project management of the study, provides pharmacovigilance services as well as using Oracle Clinical, a database management system, to provide data analysis and query management services.

ETC-206 (D3-003)

D3-003 is a Phase I clinical trial to evaluate the safety, tolerability, blood levels and target engagement of ETC-206, a novel cancer drug candidate which could be used for the treatment of blood cancers.

A uniquely “Made in Singapore” discovery, ETC-206 was discovered and developed through a collaboration between A*STAR’s Experimental Therapeutics Centre (ETC), the Drug Discovery and Development (D3) unit led by Professor Alex Matter and Duke-National University of Singapore Medical School (Duke-NUS). SCRI is coordinating the clinical research operations led by D3 with its Biostatistics, Research Monitoring, Data Management, Project Management, Pharmacovigilance, and Research Informatics departments participating in supporting the trial.
EXPEL

Extensive peritoneal lavage is a simple, inexpensive method that may prove to be an effective strategy for treatment of gastric cancer. Led by Professor Jimmy So of NUH, EXPEL is a study to investigate if extensive peritoneal lavage improves gastric cancer survival post-gastrectomy by reducing the risk of peritoneal recurrence. Funded by NMRC, a total of 16 sites from six countries are involved in this study and SCRI provides support in facilitating the external contract research organisation (CRO) for the research monitoring and subject randomisation for the EXPEL study.

PAROS 2

PAROS 2 is led by Associate Professor Marcus Ong from the Singapore General Hospital. This is a prospective registry of out-of-hospital cardiac arrest (OHCA) cases across Asia that explores predictors of OHCA outcomes in the chain of survival. The study is co-funded by several US philanthropic and pharmaceutical organisations such as the Laerdal Foundation, Laerdal Medical and Ramsey Social Justice Foundation. These overseas funds are disbursed to developing countries in Asia to support and encourage the implementation of good practices that help to improve OHCA survival. SCRI is involved in the data collection and scientific data analysis of the study, whilst administrating fund utilisation and contract management for the study.

IHN01

IHN01 is a study of head and neck cancer led by NCCS’s Professor Soo Khee Chee. Co-funded by Innogene Kalbiotech, the study is supported by two SCRI teams. The Data Management team is in charge of managing the trial data collected from study sites in Australia, Cuba, Saudi Arabia, Taiwan, South Korea, India and Singapore; the Research Informatics team is managing database accounts and the web randomisation system.

MUC-1

MUC-1 is an oncology study led by NCCS’s Associate Professor Toh Han Chong. This study underscores a tripartite partnership involving SCRI, NCCS and MicroVAX LLC. Besides taking on the trial sponsor role for the first time, SCRI is responsible for overall project management, research monitoring, safety management and quality control of the study. NCCS provides scientific lead and recruits patients for the first-in-man cancer therapeutic vaccine provided by US biotech company MicroVAX LLC.

This trial has attracted candidate subjects from overseas, and six out of seven cohorts of the trial have completed the study successfully. The success of this first-in-man trial of immunotherapy can stand to benefit cancer patients and also pioneer a collaboration model enabling smaller biotech companies to participate in first-in-man trials in Singapore.

TRUNCATE-TB

TRUNCATE-TB is led by Professor Nicholas Paton from the National University Hospital (Singapore). This study is primarily funded by the Medical Research Council of the United Kingdom to study a new treatment regime for tuberculosis involving 900 patients across several countries in Asia. SCRI is involved in the project planning, site initiation and monitoring (Singapore site), data management, pharmacovigilance and statistical analysis.
Pouring resources into research to improve survival rates

Carolyn Khew

From comparing different treatment options to developing personalised treatments, scientists are looking at how they can improve survival rates for liver cancer patients.

Only recently have pharmaceutical companies and researchers begun paying more attention to the disease, experts here told The Straits Times.

This April, a S7.5 million grant was awarded by Singapore’s National Medical Research Council to study liver cancer.

There are currently 13 clinical trials for the cancer being run at the National Cancer Centre Singapore (NCCS).

This is considered a “fairly high” number, given that the condition is not the most common cancer here, said Associate Professor Teoh Yee Leong, who is chief executive officer of the Singapore Clinical Research Institute (SCRI), which coordinates research both inside and outside the country.

The disease is the third-deadliest cancer nationally, and only about a fifth of patients with early-stage hepatocellular carcinoma (HCC) – the most common form of liver cancer – are eligible for surgery or transplantation.

Until recently, however, very little research had been done on liver cancer compared with, say, breast or colorectal cancers, said Professor Pierce Chow, a senior consultant surgeon with NCCS and Singapore General Hospital.

“Things have changed, and we now have both the scientific ability and funding to carry out research on this cancer, which is so important to our patients,” he said.

“In a way, we are making up for lost time as outcomes for liver cancer still lag significantly behind those for other common cancers.”

One reason for the increased interest is that clinicians want to improve treatment outcomes – the disease is considered a “death sentence” for those who are diagnosed in the late stages, said Prof Teoh.

“This cancer is not easy to diagnose in the early stage and, by the time the patient presents with symptoms, it is normally too late for curative treatment,” he noted.

“Thus, there is now a lot of focus on conducting research into liver cancer to look for better treatment approaches.”

A team of researchers from SCRI and NCCS is leading a clinical trial to compare two treatment methods for liver cancer.

For the trial, one group of patients is treated with the oral drug Sorafenib, which curbs the ability of cancer cells to develop, while the other group is treated with a targeted radiation therapy.

Sorafenib is currently the only targeted drug approved for use against liver cancer and is commonly used for patients with an advanced form of the disease.

The trial has completed its recruitment of 360 participants from various Asian countries, including Thailand, the Philippines and Myanmar.

Researchers are now in the process of analysing the results to find out which treatment option works better, said Prof Teoh.

Results are expected to be out next year.

“Each country by itself might not have sufficient numbers of patients to analyse the research findings but, pooling together all the data collected in these countries, we can analyse the data and find out which treatment options are the best for patients in Asia,” said Prof Teoh.

“Ultimately, the results will benefit not just patients in Singapore but also patients in Asia.”

Separately, a team comprising clinicians and researchers from several institutions will carry out in-depth studies on the genomics and immunology of liver cancer.

Recruitment for the trial has since started.

kcarolyn@sph.com.sg
Researchers studying customised treatments for liver cancer patients

By Loh Chuan Junn | 12 Oct 2016 03:44PM

SINGAPORE: A local research team is looking to recruit 40 Singaporean or permanent resident (PR) liver cancer patients for a study on personalised therapies for liver cancer patients, the National Cancer Centre Singapore (NCCS) said on Wednesday (Oct 12).

The researchers from NCCS, the National University Health System (NUHS) and the Singapore General Hospital (SGH) are seeking patients who have Hepatocellular Carcinoma (HCC) – the most common type of liver cancer – and are scheduled for surgery.

Senior Consultant Surgeon of NCCS and the lead principal investigator for the project Professor Pierce Chow said HCC is “particularly complex at the genomic and immunology level”, and each patient needs to have therapy targeted at his individual physical makeup.

However, Prof Chow said there was currently not enough scientific information for personalised treatment, or “precision therapy”, for individual liver cancer patients based on the characteristics of their cancers, such as the mutation type.

At present, about 50 to 80 per cent of those with liver cancer – the third deadliest cancer in Singapore – suffer a recurrence within five years post-surgery, according to the NCCS. About 50 to 90 per cent of recurrent cases die from it.

Patients who participate in the study will be closely monitored by doctors, with regular follow-ups every three months for the next three years. Once their tumours are removed, researchers will take samples to study genetic changes that could have caused the cancer, how it functions and evolves and how the cancer evades the body’s immune system.

The study is part of a wider regional project involving Malaysia, Thailand and the Philippines, who will each recruit 20 participants from their countries. The S$7.5 million grant for the study comes from Singapore’s National Medical Research Council’s Translational and Clinical Research Flagship Programme.

Other research institutions collaborating in the study include the Genome Institute of Singapore, SingHealth Translational Immunology and Inflammation Centre, Singapore Clinical Research Institute (SCRI) and the Cancer Science Institute of Singapore.
七医疗机构跨国研究肝癌起因

研究人员将在未来三年内，分析国内外100名肝癌病患的癌症肿瘤样本，从中了解他们的癌细胞基因和免疫体结构，并为每位患者制定精准的治疗方案。

中国科学技术大学、中国医学科学院、中国工程院院士、中国科学院、中国疾病预防控制中心所，以及新加坡癌症研究机构，携手展示在肝癌研究上的治疗新进展。

研究人员将在未来三年内，分析国内外100名肝癌病患的癌症肿瘤样本，从中了解他们的癌细胞基因和免疫体结构，并为每位患者制定精准的治疗方案。研究组在每三至六个月会定期跟进病患的情况，以了解治疗效果。

研究计划由研究员梁秀琴教授领导。她表示，目前的治疗药物可能并不适合所有的病患，因此需要发展出更精准的治疗方法。她指出，“中国的癌症研究仍然存在一些挑战，我们需要更深入地了解肝癌的起因和治疗方法，以便为患者提供更精准的治疗方案。”


IN SEARCH OF BETTER TREATMENTS FOR OUR PATIENTS

有助延缓病情恶化
“新加坡制造”抗糖尿病药料三年后面市

这种名为 DAA-1 的新抗糖尿病药物，主要针对第二型糖尿病患者。这种疾病来自身体内的慢性胰岛素抵抗，这种慢性胰岛素抵抗使身体不能有效利用胰岛素。DAA-1 可以通过减少慢性胰岛素抵抗，从而延缓病情恶化。

新药的开发

专家表示，这种药物的开发是一个长期过程，从实验室研究到临床试验，需要数年时间。在新加坡临床试验机构进行的临床试验结果表明，DAA-1 能有效降低第二型糖尿病患者的血糖水平，同时减少胰岛素的使用量。

DAA-1 的未来

新加坡卫生部长表示，尽管 DAA-1 的开发过程漫长，但其疗效显著，值得期待。政府将继续支持生物技术的发展，为糖尿病患者带来更多的希望。

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## OUR MILESTONES

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<tr>
<td><strong>2008</strong></td>
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<tr>
<td>▶ Transition to SCRI and transfer of over 20 clinical trials and other research studies</td>
<td>▶ Establishment of Family Medicine Research Network (FMRN)</td>
<td>▶ Chairing of the Clinical Trial Operational Efficiency Review working group (COERWG) by SCRI</td>
<td>▶ GET Workshop on Medical Devices, the first of a series of collaborations with A*STAR’s Biomedical Engineering Programme</td>
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<td><strong>2009</strong></td>
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<td>▶ First Grant Enhancement Training (GET) workshop</td>
<td>▶ First study using Electronic Data Capture (Oracle Clinical) system</td>
<td>▶ First conference collaboration with industry partner, ORACLE Health Sciences</td>
<td>▶ PAROS CRN: Award of the Ministry of Health’s Health Services Research grant</td>
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<td>▶ Appointment of Scientific Advisors</td>
<td>▶ Establishment of the Pan-Asian Resuscitation Outcomes Study (PAROS) CRN</td>
<td>▶ Setting up of the Quality Assurance (QA) Department</td>
<td>▶ Second grant award from Tanoto Foundation for the Metabolic Research Network CRN</td>
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<td>▶ Establishment of Dementia Clinical Research Network</td>
<td>▶ Establishment of Metabolic Research Network (MRN)</td>
<td>▶ First workshop collaboration with industry partner, Merck Pte Ltd</td>
<td>▶ First patient recruited for FMRN study</td>
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<td>▶ First study using Electronic Data Capture (REDcap) system</td>
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<td>▶ Appointment of new CEO</td>
<td>▶ First sponsor role by SCRI in a first-in-man trial (MUC-1)</td>
<td>▶ Appointment of new Chairman</td>
<td>▶ Establishment of the Regional Liver Cancer Registry by SCRI, National Cancer Centre Singapore (NCCS) and QuintilesIMS to collect more data on liver cancer. The Registry will monitor about 2,000 liver cancer patients from Singapore and up to eight Asian countries in order to study the cost and treatment options for primary liver cancer</td>
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<td>▶ Collaboration with the Singapore Biomedical Sciences Industry Partnership Office (BMS IPO): Phase 1 of the Stratified Medicine effort in Diabetes</td>
<td>▶ Inauguration of the Clinical Research Network (CRN) Forum</td>
<td>▶ Launch of the National Clinical Trial Insurance Policy</td>
<td>▶ Celebration of SCRI’s 20 years of clinical research from SCRI’s origins as the Clinical Trials and Epidemiology Research (CTERU)</td>
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<tr>
<td>▶ Collaboration with the National University of Singapore-Master of Clinical Investigation (NUS-MCI) for Clinical Trials Operations workshop</td>
<td>▶ Announcement by SCRI, KKH, Duke-NUS and NUS YLLSOM researchers of research funding on administration of epidurals to women during childbirth</td>
<td>▶ Launch of SCRI’s SG50 commemorative book, Saving Lives through Clinical Research: A 50-year Journey of Singapore’s Scientific Leadership</td>
<td>▶ Recruitment completed for landmark Investigator-initiated trial, AHCC06. Funded by the National Medical Research Council (NMRC) and Sirtex, the study was launched in 2010 and involved 28 medical centres in 11 Asia-Pacific countries</td>
</tr>
<tr>
<td>▶ Participation in the inaugural A*STAR MedTech Convention 2013</td>
<td>▶ Additional funding of $1.9 million to the Asia-Pacific Hepatocellular Carcinoma Trials Group from Sirtex</td>
<td>▶ Completion of the first-in-man, “Made in Singapore” drug in Phase 1 trial (DAA-1) in NUHS</td>
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GEOGRAPHICAL COVERAGE
SCRI has a far-reaching local and international presence
IN SEARCH OF BETTER TREATMENTS FOR OUR PATIENTS

SINGAPORE

1. Changi General Hospital
2. Duke-NUS Medical School, Singapore
3. Institute of Mental Health
4. John Hopkins Singapore Internal Medicine Centre
5. Jurong Medical Centre
6. Khoo Teck Puat Hospital
7. KK Women’s and Children’s Hospital
8. National Cancer Centre Singapore
9. National Dental Care Singapore
10. National Heart Centre Singapore
11. National Neuroscience Institute
12. National Skin Centre
13. National University Cancer Institute, Singapore
14. National University Heart Centre, Singapore
15. National University Hospital
16. National University of Singapore, Faculty of Dentistry
17. National University of Singapore, Yong Loo Lin, School of Medicine
18. Ng Teng Fong General Hospital
19. Sengkang Health, Alexandra Hospital
20. Singapore General Hospital
21. Singapore National Eye Centre
22. SingHealth Investigational Medicine Unit
23. St. Luke’s Hospital
24. Tan Tock Seng Hospital
# INTERNATIONAL RESEARCH COLLABORATION SITES

**AUSTRALIA**
- Austin Health Cancer Clinical Trials
- Ballarat Regional Integrated Cancer Centre
- Barwon Health Andrew Love Cancer Centre
- Border Medical Oncology Research Unit
- Calvary Mater Newcastle Hospital
- Central Coast Cancer Centre, Gosford Hospital
- Chris O’Brien Lifehouse
- Coffs Harbour North Coast Cancer Institute, NSW
- Flinders Medical Centre
- Goulburn Valley Health, VIC
- Lyell McEwin Hospital
- Macarthur Cancer Therapy Centre
- Monash Health Medical Oncology
- Newcastle Private Hospital
- North Coast Cancer Institute Port Macquarie
- Northern Cancer Institute, NSW
- Northwest Cancer Centre Tamworth
- Orange Health Service
- Peter MacCallum Cancer Centre
- Royal Brisbane and Women’s Hospital
- Royal Darwin Hospital, Alan Walker Cancer Centre
- Royal Darwin Hospital, Northern Territory
- Royal Hobart Hospital
- Sir Charles Gairdner Hospital
- Southwest Oncology, VIC
- St John of God Subiaco
- The Tweed Hospital
- Townsville Hospital

**BANGLADESH**
- International Centre for Diarrhoeal Disease Research

**BRUNEI**
- Brunei Cancer Centre

**CHINA**
- Affiliated Hospital of Nantong University
- Beijing University Cancer Hospital
- Guangdong General Hospital
- Guangdong Provincial Cardiovascular Institute
- Jinan Central Hospital
- Nanjing First Hospital
- Qingdao Eye Hospital
- Second Affiliated Hospital of Zhejiang University
- Shandong Eye Hospital
- Shanghai Chest Hospital
- Sun Yat Sen University Cancer Centre
- The First People’s Hospital of Foshan
- The Sixth Affiliated Hospital
- Xiamen Eye Centre
- Yantai Yuhuangding Hospital
- Zhongshan City People’s Hospital

**HONG KONG**
- Alice Ho Nethersole Hospital
- Hong Kong Eye Hospital
- Prince of Wales Hospital
- Queen Mary Hospital

**INDIA**
- All India Institute of Medical Science
- Amrita Institute of Medical Sciences and Research Centre
- Aravind Eye Hospital
- Christian Medical College
- G. Kuppuswamy Naidu Memorial Hospital
- Kidwai Memorial Institute of Oncology
- LV Prasad Eye Institute
- Mazumdar Shaw Cancer Centre
- Nizam’s Institute of Medical Science
- Regional Cancer Centre Trivandrum
- Tata Memorial Hospital

**INDONESIA**
- Denpasar General Hospital
- Cipto Mangunkusumo General Hospital (RSCM)
- Dharmais Hospital National Cancer Centre
- Dr Soetomo Hospital
- Faculty of Medicine University of Indonesia
- Hasanuddin University
- Jakarta Eye Center
- Rumah Sakit Dr. Sardjito Jogjakarta
- Sanglah General Hospital
- University of Indonesia
- University of Padjadjaran

**JAPAN**
- Chiba University Hospital
- Chugoku Central Hospital
- Eguchi Eye Hospital
- Gunma University Hospital
- Hiroshima Red Cross Hospital & Atomic-bomb Survivors Hospital
- Ideta Eye Hospital
- Iwate Medical University
- Kansei Rousai Hospital
- Kobe City Medical Center General Hospital
- Kokushikan University
- Komaki City Hospital
- Kyoto Prefectural Medical University
- Miyata Eye Hospital
- National Hospital Organization Disaster Medical Center
- Northern Fukushima Medical Center
- Ogaki Municipal Hospital
- Okamoto Eye Clinic
- Osaka University Graduate School of Medical Hospital
- Otemae Hospital
- Sapporo medical university hospital
- Tokai Central Hospital
- Tokushima Prefectural Central Hospital
- Tottori University Hospital
- University of Toyama
MALAYSIA
Hospital Raja Permaisuri Bainun
Hospital Kuala Lumpur
Hospital Universiti Kebangsaan Malaysia
Institut Jantung Negara
Institute of Respiratory Medicine
International Specialist Eye Centre
Mahkota Medical Centre
Pantai Hospital Kuala Lumpur
Penang Adventist Hospital
Penang General Hospital
Sarawak General Hospital
University Malaya Medical Centre
University of Malaysia

PAKISTAN
Aga Khan University

PHILIPPINES
Baguio General Hospital and Medical Center
Brokenshire Hospital
Cebu Velez General Hospital
Chong Hua Hospital
Davao Doctors Hospital
Davao Medical Center
Davao Medical School Foundation
De La Salle Hospital
East Ave Medical Center
Jose Reyes Memorial Medical Center
Lung Center of the Philippines
Makati Medical Center
Perpetual Succour Hospital
Philippine General Hospital
Quezon Institute
St. Luke’s Medical Center
The Medical City
Tropical Disease Foundation
University of Santo Tomas Hospital
Visayas Community Medical Center
West Visayas State University Medical Center

SOUTH KOREA
Ajou University Hospital
Asan Medical Center
Bundang Seoul National University Hospital
CHA Bundang Medical Center
Cheonnam University Hwasoon Hospital
Dong-A University Hospital
Gachon University Gil Hospital
Hallym University Sacred Heart Hospital
INHA University Hospital
Kim’s Eye Hospital
Korea University Anam Hospital
National Cancer Centre Korea
Samsung Medical Center
Seoul National University Hospital
Severance Hospital, Yonsei
St Mary’s Hospital
St Vincent’s Hospital

TAIWAN
Chang Gung Memorial Hospital, LK
China Medical University Hospital
Koo’s Foundation SYS Cancer Center
Mackay Memorial Hospital
National Cheng Kung University
National Taiwan University Hospital
Shuang Ho Hospital
Taiichung Veteran’s General Hospital
Taipei Medical University Hospital
Taipei Tzu Chi General Hospital
Taipei Veterans General Hospital
Tungs Taichung Metroharbor hospital
Wan Fang Hospital

THAILAND
Central Chest Institute of Thailand
Chiang Mai Hospital
Chiang Mai University Hospital
Chulabhorn Hospital
Chulalongkorn Hospital
King Chulalongkorn Memorial Hospital
Mahidol University
National Cancer Institute Thailand
Phramongkutklao Hospital
Prasat Neurological Institute
Siriraj Hospital
Thammasat University Hospital

SOUTH AFRICA
GVI Capegate
The Oncology Centre

VIETNAM
Ho Chi Minh City Eye Hospital
National Hospital of Pediatrics
Vietnam National Institute of Ophthalmology
While SCRI supports multi-site clinical trials spanning many countries, at the heart of its clinical research is its focus on Singapore’s key health issues and diseases that affect Asian patients.
Singapore has one of the highest rates of myopia in the world. Short-sightedness affects 28 percent of children as young as seven years old, and the rate increases to 83 percent when they reach 18 years old.

While myopia can be corrected by optical glasses, the functional impact relating to both occupational and lifestyle restrictions should not be underestimated.

Most importantly, studies have shown that persons with higher myopia are at higher risks of developing complications such as degenerative retinal changes, early-onset cataracts (in the thirties to forties) and open-angle glaucoma that can be sight-threatening later in life. Children who start developing myopia at a younger age are more likely to ultimately develop high myopia later in life, and high myopia currently occurs in at least 15 percent of our 18-year-olds in Singapore.

Based on previous ATOM trials and epidemiological studies, the ATOM3 trial continues to investigate the use of low dose Atropine to prevent and control myopia in the younger population. The study is sponsored by National Medical Research Council (NMRC) and Asia Cornea Foundation (ACF).

As a result of previous trials, we now know that Atropine can reduce or slow down myopia progression in children, at least above the age of six years. The ATOM3 study, supported by SCRI, will be performed at the Singapore Eye Research Institute (SERI) and the Singapore National Eye Centre (SNEC). This new study hopes to determine if Atropine eye drops can prevent or slow the onset of myopia in young children (with myopic parents) who have a high risk of developing myopia, or reduce myopia progression in those with low myopia at a younger age.

SCRI’s project manager provides advice to both the study and internal teams, clinical research associates for site initiation and monitoring, as well as biostatistics and pharmacovigilance support. SCRI’s Research Informatics department developed the Randomisation platform (RAND) for the project by working with the biostatistician. In addition, a data manager will be working closely with the Principal Investigator (PI) and biostatistician to customise the Oracle Clinical as well as provide data analysis and query management.
THE ATOM3 PROJECT TEAM

Front row (from left to right):
Dr Grace Wu (SNEC), Dr Lu Qingshu (SCRI), Ivanus Manopo (SCRI), Professor Donald Tan (SNEC), Associate Professor Audrey Chia (SNEC), Adjunct Assistant Professor Yvonne Ling (SNEC), Dr Tay Su Ann (SNEC), Professor Cheung Yin Bun (Duke-NUS)

Back row (from left to right):
Liew Wei Ming (SCRI), Tan Siew Hoon (SCRI), Fong Yee Wei (SERI), Goon Yar Yen (SERI), Lee Jia Yi (SERI), Aw Ai Tee (SNEC), Lai Hwei Ching (SNEC), Toh Ai Nee (SERI), Ng Xuanhui (SCRI), Evelin Tan (SERI), Swetha Gangishetty (SCRI), Michelle Liew (SCRI), Marlina Tay (SERI), Khoo Wei Zhi (SCRI), Lim Hui Qing (SCRI)
We hope to determine if Atropine eyedrops can actually prevent or slow the onset of myopia in young children with myopic parents. Results from this study will influence the way we manage myopia in our community. We look forward to working with SCRI on this project.

Associate Professor Audrey Chia, Principal Investigator of ATOM3
If the Atropine eye drops in this study are successful in preventing the onset of myopia or myopia progression in these high-risk children, then they may also reduce the risk of high myopia and its complications when the children become adults.

Professor Donald Tan, Co-Principal Investigator of ATOM3
Hepatocellular carcinoma (HCC) is the sixth most common cancer in the world (5.6%), the second most common cause of cancer deaths, and afflicts approximately 800,000 people yearly*.

Real world data is crucial to an understanding of the disease effect and relevance. This investigator-initiated registry has therefore been established with the aim to provide a complete longitudinal picture of the HCC patient journey in several representative Asia-Pacific countries.

A first in the world, the HCC Registry is designed as a multi-national longitudinal cohort study of patients diagnosed with HCC between 1 January 2013 and 30 June 2018 in nine countries: Korea, Taiwan, Thailand, Japan, China, Hong Kong, Australia, New Zealand and Singapore.

The National Cancer Centre Singapore (NCCS), the Asian HCC Physician Network and SCRI are partnering QuintilesIMS for the development of the registry.

The SCRI team brings to this partnership our strength in coordinating the data collection in these countries which are within our Asia Hepatocellular Carcinoma (AHCC) trials network. We also design and manage the database for analysis.

Data from the Registry can help policymakers and healthcare professionals formulate strategies to manage liver cancer patients as collection and analysis of epidemiologic HCC data will play a critical role in guiding future disease prevention strategies and optimising patient management.

This public-private collaboration will also provide invaluable information to the pharmaceutical industry, governmental and insurance payers and physicians. It does so by delivering a complete longitudinal picture of the disease using a combination of associated (retrospective and prospective) clinical health costs and patient-reported outcomes data.

The Registry will help to answer important questions such as different treatment patterns/strategies; healthcare resource use and costs of treatments; as well as first-hand insights to patients’ perspectives on their treatments.

Using this real world data, government planning agencies and pharmaceutical companies can benefit through bespoke analytics to establish their clinical development and product strategies. Healthcare payers will have a good understanding of the disease burden and budget impact to better craft the public health policies. Physicians will be able to use this data to better optimise care pathways enhancing treatment outcomes for HCC patients.

The study aims to conduct analysis in the nine countries on:
- Patient demographics
- Diagnosis, treatments and disease outcomes
- Healthcare resource use
- Direct and indirect costs to HCC management
- Patient health-related quality of life

*According to Stewart and Wild, 2014.
THE AHCC REGISTRY PROJECT TEAM

Front row (from left to right):
Lynette Lai (SGH), Huang Ruiping (SCRI), Professor Pierce Chow (NCCS), Chew Sin Chi (NCCS), Fiona Ni Ni Moe (NCCS), Christopher King (QuintilesIMS), Wu Ling Yan (NCCS)

Back row (from left to right):
Jane Yeo (QuintilesIMS), Su Jie (SCRI), Liang Ai Leng (NCCS), Phang Su Ting (NCCS), Sherlynn Tan (NCCS), Rachel Choi (NCCS), Evonne Poon (QuintilesIMS)
Although HCC is such an important cancer, our current understanding of its diversity and clinical trajectory is actually very scanty. Data from clinical trials are from patients who are strictly selected and may not be representative of patients in general. Important scientific and policy decisions need to be based on real world data. This registry will be the first such multinational registry in the world for HCC.

Professor Pierce Chow, Principal Investigator of AHCC Registry
THE COLEUS PROJECT
Pain Management During Labour and Delivery

Labour pain could be one of the worst pains a woman may ever experience in her lifetime. The COLEUS study is a single-centre randomised controlled trial comparing two novel epidural delivery systems developed at KKH with conventional patient-controlled epidural analgesia to reduce the incidence of breakthrough pain. Breakthrough pain is the unscheduled epidural dosing given by the anaesthetists due to inadequate pain relief despite being on epidural analgesia during labour.

The study started in early 2015 and recruitment is in progress for first-time mothers with full-term pregnancies; these mothers are assessed on their degree of satisfaction, pain and psychological vulnerability.

According to COLEUS’s lead researcher, Associate Professor Sng Ban Leong, who is also Deputy Head and Senior Consultant, Department of Women’s Anaesthesia, and Director, KK Research Centre at KKH, women who experience increased pain during labour could be at higher risk of dysfunctional labour requiring obstetric intervention such as caesarean section or instrumental delivery. Hence, by improving the ability to detect, intervene and prevent a mother’s pain during labour, there is a reasonable opportunity to reduce maternal distress and anxiety, improving outcomes for both mother and baby.

The study is funded by the National Medical Research Council (NMRC) and is a multidisciplinary collaboration involving researchers from KKH’s Department of Women’s Anaesthesia, Division of Obstetrics and Gynaecology and Department of Psychological Medicine as well as Duke-NUS Medical School and SCRI. It also receives industrial partner support from Innovfusion.

SCRI Biostatistics supports COLEUS in statistical analysis and manuscript-writing.
THE COLEUS PROJECT TEAM

Front row (from left to right):
Agnes Teo (KKH), Dr Chua Tze-Ern (KKH), Dr Tagore Shephali (KKH), Dr Dianne Bautista (SCRI), Associate Professor Sng Ban Leong (KKH), Professor Alex Sia Tiong Heng (KKH)

Back row (from left to right):
Liu Juan (KKH), Yvonne Yong (KKH), Dr Tan Chin Wen (KKH), Dr Farida Ithnin (KKH), Dr Reena Han Nianlin (KKH), Ms Maria Binte Jumhasan (KKH), Gabriel Tan (Innovfusion), Theodore Tan (Innovfusion)
We hope this study will help reduce the level of pain for women in labour and enable a more positive birthing experience. The partnership with SCRI is a rewarding one.

Associate Professor Sng Ban Leong, Principal Investigator of COLEUS
Prostate cancer is the second most common cancer in the world for men. One of the treatment options for prostate cancer is the use of hormonal treatment. However, recently developed therapies for Castration-Resistant Prostate Cancer (CRPC) by hormone has not been effective for 20 to 40 percent of CRPC patients.

One of the postulated mechanisms for this resistance is the development or presence of androgen receptor splice variants. ARV7 aims to find out the prevalence and incidence of the AR-V7 splice variant in an Asian population of patients with CRPC and to study how different treatments impact the patient outcomes in this group of patients.

The study is co-funded by global pharmaceutical company Sanofi and National Medical Research Council (NMRC). There are eight participating sites within key hospitals in five countries: Singapore, Malaysia, Hong Kong, Thailand and Japan. SCRI supports the project management and prepares sites in Singapore for study initiation.

SCRI provides support for the study by allocating a project manager as the main point of contact for sites and internal teams, a clinical research associate to assist sites with approval processes and a pharmacovigilance team for serious adverse event (SAE) reporting. The data manager from SCRI works closely with the Principal Investigator (PI) and biostatisticians to custom-build a database management system, Oracle Clinical, in addition to providing data analysis and query management services.

ARV7 is unique: It would provide data for comparisons with recent publications and study the effect of the AR-V7 variant on the Asian population. It also showcases the successful partnership between a private global pharmaceutical company, Sanofi, with our public institutions, National Cancer Centre Singapore (NCCS) and SCRI.
THE ARV7 PROJECT TEAM

Front row (from left to right):
Dr Ravindran Kanesvaran (NCCS), Associate Professor Chong Kian Tai (TTSH)

Back row (from left to right):
Chong Wan Ling (SCRI), Doreen Leow (SCRI), Wendy Zhao (SCRI), Tan Hui Shan (NCCS), Ong Whee Sze (NCCS), Swetha Gangishetty (SCRI), Hilary Chua (TTSH)
This study is important for us as it would help us understand how common this subgroup of prostate cancer patients is in Asia and what treatment options are available for them. As our research partner, SCRI has supported us in important operational aspects of the study.

Dr Ravindran Kanesvaran, Principal Investigator of ARV7
Phase I Study of Made in Singapore Cancer Drug

D3-003 is a Phase I clinical trial to evaluate the safety, tolerability, blood levels, and target engagement of ETC-206, a novel cancer drug candidate which could be used for the treatment of blood cancers. The three main groups of blood cancer are leukaemia, lymphoma and myeloma, two of which (leukaemia and lymphoma) are among the 10 types of cancer with the highest mortality rates in Singapore.

ETC-206 is the first Mnk-inhibitor capable of targeting the enzyme in liquid cancers to suppress cancer proliferation and prevent cancer progression. This offers a therapeutic strategy that could potentially lower the mortality rates caused by blood cancers.

A uniquely “Made in Singapore” discovery, ETC-206 was discovered and developed through a collaboration between A*STAR’s Experimental Therapeutics Centre (ETC), the Drug Discovery and Development (D3) unit, and Duke-National University of Singapore Medical School (Duke-NUS), a partnership which began in May 2010.

The study team also comprised:
- a clinical site at the SingHealth Investigational Medicine Unit (IMU), located at the Singapore General Hospital (SGH) in Singapore
- an academic CRO at Singapore Clinical Research Institute (SCRI)
- a central lab, Quest Laboratories from Singapore
- three vendors from France (SGS, Phinc and CEMO for PD marker and PK data analysis)
- a vendor from US (ERT, ECG monitoring)
- a vendor from India (CDISC submission)

The drug was developed through a complex series of laboratory and clinical research with the aim of identifying better treatment options for our patients. The study showcases the capabilities and strong partnerships between Singapore research teams, evident in their creation of a new milestone in cancer drug development.

SCRI is coordinating the clinical research operations led by D3. SCRI’s coordination services range from biostatistics, research monitoring, data and project management, pharmacovigilance to research informatics. Phase 1 trials will evaluate the safety, tolerability, blood levels, and target engagement of ETC-206 in up to 17 healthy volunteers.
THE ETC-206 (D3-003) TEAM

Front row (from left to right):
Dr Vincenzo Teneggi (D3, A*STAR), Dr Kantharaj Ethirajulu (D3, A*STAR), Mihir Gandhi (SCRI), Huang Ruiping (SCRI), Doreen Leow (SCRI), Professor Alex Matter (ETC and D3, A*STAR), Lim Hui Qing (SCRI), Khoo Wei Zhi (SCRI), Maryam Yasin (D3, A*STAR), Tan Siew Hoon (SCRI)

Back row (from left to right):
Ganesh Lekurwale (SCRI), Ng Xuanhui (SCRI), Kelvin Ang (SCRI), Dr Dhananjay Umranl (D3, A*STAR), Dr Pauline Yeo (D3, A*STAR), Dr Cao Yang (SCRI), Dr Lu Qingshu (SCRI), Dr Veronica Diermayr (D3, A*STAR), Dr Ranjani Nellore (D3, A*STAR)
Front row (from left to right): Doreen Leow (SCRI), Dr Greg Li (Singhealth IMU), Dr Matthew Ng (Singhealth IMU), Associate Professor Darren Lim (Singhealth IMU), Ng Siok Ting (SCRI), Dr Cao Yang (SCRI)

Back row (from left to right): Jacqueline Teo (Singhealth IMU), Dr Lu Qingshu (SCRI), Tay Bo Hong (Singhealth IMU), Lim Hui Qing (SCRI), Shayne Lin (Singhealth IMU), Pek Li Ping (Shirley) (Singhealth IMU), Ramya Murugayee (Singhealth IMU), Kelvin Ang (SCRI), Ma Elnora Galor Gasacao (Singhealth IMU), Low Geok Khim (Singhealth IMU), Anna Lorraine San Gabriel Surio (Singhealth IMU), Alice Chan (Singhealth IMU), Tan Choon Ping (SCRI), Robyn Yip (Singhealth IMU), Ganesh Lekurwale (SCRI), Khoo Wei Zhi (SCRI), Jeeva Lavanya Lakshmi (Singhealth IMU)
The growth of Singapore’s biomedical sector, and our increasingly advanced drug development expertise, are anchored on an integrated R&D ecosystem and strong partnerships with the clinical community. Our collaboration with Duke-NUS and SCRI highlights how research and clinical players can work together to achieve breakthroughs in cancer therapeutics.

Professor Alex Matter, Chief Executive Officer, ETC and D3
THE CEA PSYEDU PROJECT

Nursing Research for Post-Natal Wellbeing

The effectiveness and cost-effectiveness of web-based and home-based postnatal psychoeducational interventions for first-time mothers: A randomised controlled trial

CEA PsyEdu is a randomised controlled trial in Singapore. The trial aims to (1) develop a web-based postnatal psycho-educational programme for first-time mothers, (2) examine its effectiveness on maternal self-efficacy in newborn care (primary outcome), as well as social support, psychological well-being and maternal satisfaction with the postnatal support (secondary outcomes) and (3) evaluate its cost-effectiveness as compared to home-based psycho-educational programme and routine postnatal care.

Supported by the NMRC Health Services Research Competitive Research Grant (HSR CRG), this project shows novelty in designing and promoting a psycho-educational programme for first-time mothers. The study leverages on information technology to provide innovative and high quality nursing care that is efficient, potentially cost-effective and evidence-based. This trial shows great potential of having a big impact on women going through childbirth.

SCRI’s Epidemiology Department harnesses its expertise to provide the project with cost-effectiveness analysis and economic evaluation. Playing a key role for this project in the design of CRFs, development of cost-effectiveness analysis plan, construction of Markov models, and support of manuscript drafting. The department hopes this study will pave the way for greater development of research projects to promote cost-effective health services in the nursing field.
THE CEA PSYEDU PROJECT TEAM

Front row (from left to right):
Associate Professor Edwin Chan (SCRI), Associate Professor He Hong-Gu (NUS), Associate Professor Chong Yap Seng (NUH)

Back row (from left to right):
Associate Professor Luo Nan (NUS), Jiao Nana (NUS), Dr Shi Luming (SCRI), Dr Shefaly Shorey (NUS), Dr Leta Wei Ling Loh (NUH)
We hope this project will help first-time mothers when they go through childbirth, an important period in their lives so that they are confident and happy through Postnatal psychoeducational intervention.

Associate Professor He Hong-Gu, Principal Investigator of CEA PsyEdu
THE EXPEL PROJECT

Extensive Peritoneal Lavage after Curative Gastrectomy for Gastric Cancer: a Randomised Controlled Trial

The objective of the Expel study is to assess whether by reducing the risk of peritoneal recurrence, extensive peritoneal lavage improves overall survival of gastric cancer patients undergoing gastrectomy.

In this study funded by National Medical Research Council (NMRC), 16 sites from six countries are involved. These countries include Singapore (two sites), China (two sites), Hong Kong (two sites), Japan (three sites), Korea (six sites) and Malaysia (one site).

This study was initiated in March 2015. By February 2016, 539 subjects had been enrolled in the EXPEL study. The recruitment is still ongoing to meet its recruitment target of 800 subjects.

Extensive peritoneal lavage is simple, inexpensive, and carries minimal risk to patients, but this simple method may be an effective strategy for treatment of gastric cancer.

Both SCRI’s Project Management and Research Informatics departments provide support for the EXPEL study. The project manager tracks the overall study status of all study sites while facilitating the work of external contract research organisation (CRO) engaged for study monitoring and management services at sites in China and Korea. In addition, the Research Information department provides study randomisation for all the study sites.
THE EXPEL PROJECT TEAM

Front row (from left to right):
Dr Yong Wei Peng (NUH), Professor Jimmy So (NUH), Associate Professor Tai Bee Choo (NUS)

Back row (from left to right):
Dr Asim Shabbir (NUH), Elya (NUH), Janelle Phua (NUH), Dr Li Xinhua (SCRI), Dr Kim Guowei (NUH), Teo Siok Chin (NUH), Jana Chan (NUH), Huang Ruiping (SCRI)
If the result of this study is positive, it would demonstrate that adding a simple step in doing more extensive peritoneal lavage, at very minimal additional cost, manages to improve the survival chances of gastric cancer which will be beneficial to our patients. We are grateful for the support provided by the SCRI team in coordinating the data collection overseas.

Professor Jimmy So,
Principal Investigator of EXPEL
Over the past two decades, our organisation’s scope of capabilities and operations has grown. Today, SCRI offers not only epidemiology and biostatistics support in clinical research, but also support in the areas of clinical trial operations and logistics, including project management, data management, research monitoring, and research informatics.

Associate Professor Teoh Yee Leong
CEO, SCRI
With its unique Singapore base but Asian-centric focus, SCRI is able to stay at the forefront of clinical research excellence in and ever-changing biomedical landscape.
Evidence-based treatments and practices are critical for optimising patient care using clinical research conducted locally and in other parts of the world. In turn, the quality of evidence depends on study design, sample sizes and conduct of the study.

To optimise research efforts, SCRI’s Biostatistics department helps clinicians in designing studies, selecting optimal sample size and synthesising evidence generated from the study results.

Since its establishment in the early days of CTERU, the Biostatistics department has supported more than:

- 100 studies
- 150 grant proposals
- 200 research papers
- 200 workshops/seminars
- 1000 research consultations

The department has evolved to become a scientific reviewer for grant agencies, scientific journals, ethics bodies and pharmaceutical companies. It is also involved in training medical and biostatistics students for study designing and grant proposal writing, thus ensuring that future generations of clinical researchers have the basic skills to produce quality studies.
OUR BIOSTATISTICS TEAM

From left to right: Ganesh Lekurwale, Wei Yuan, Rajesh Moorakonda, Dr Lu Qingshu

Not in picture: Mhir Gandhi (HOD), Dr Dianne Bautista
EVIDENCE SYNTHESIS SERVICES COMPRIS

- Development of systematic methodology to promote evidence-based medicine
- Conducting synthesis of qualitative and quantitative evidence to evaluate efficacy and cost-effectiveness
- Use of systematic reviews to identify knowledge gaps, assess health services and inform decision-making
- Support production of high quality systematic reviews for the Cochrane Collaboration

SCRI's Epidemiology team supports the practice of evidence-based medicine by developing and teaching review methodologies.

Our staff have both clinical and research methodology training to ensure the successful conduct of high quality and clinically relevant systematic reviews and evidence syntheses.

Through conducting tailor-made and interactive training workshops, we actively contribute our expertise to help clinical researchers in evidence synthesis.

In recent years, we have shifted our focus from traditional interventional studies to meet the emerging demand for evidence synthesis in health economic evaluation and diagnostic test accuracy projects. We are also expanding our training and education activities to cover these new emerging interests. Through these endeavours, we hope to encourage more local researchers in contributing to filling in knowledge gaps by taking on impactful systematic reviews.

KEY PROJECT(S)

**Systematic reviews**

- Immunosuppression in Liver Transplantation [Asian Liver Transplantation Network (ALTN) Expert Panel Meeting]
- Novel techniques for sentinel lymph node biopsy in breast cancer: a systematic review (Network Meta-analysis and systematic review of cost-effectiveness)
- Oesophageal pH studies in patients with persistent gastroesophageal reflux symptoms despite proton pump inhibitor (PPI) therapy. Should studies be performed on or off PPIs? A systematic review and meta-analysis
- Effects of Aortic Valve Replacement on the Prognosis of Severe Aortic Stenosis and Preserved Systolic Function (Network Meta-analysis)
- Drug Induced Liver Injury (DILI) in the East: a systematic review
- Non-steroidal anti-inflammatory drugs (NSAIDS) for trigger finger (Cochrane systematic review)
HEALTH OUTCOMES RESEARCH EXPERTISE COMPRIS ES

- Development of high quality study protocols for health outcomes and health economic evaluation projects
- Support of research grant applications
- Support of post-grant activities such as CRF design, data analysis and reporting
- Evaluation of health services programmes
- Development of hospital-based disease registries

Our epidemiology and health economics teams have extensive experience in collaborating with clinical domain experts to develop quality protocols for health outcomes research, health economic evaluation and health technology assessment projects.

We advise on all aspects of protocol design to meet regulatory and funding requirements, providing guidance to create a feasible and rigorous study protocol.

With our medical training, clinical research foundations and vast research experience, we are the clinicians’ ideal partners to help quickly translate a research question into a valid and feasible research plan.

Health outcomes investigations not only improve the potential to provide the best care at the lowest cost to our patients but also influence the formation of healthcare policies relevant to our population’s needs.

Currently, the Epidemiology department forms the nucleus of health economic evaluation expertise at SCRI, and we provide technical support to help local clinical researchers incorporate health economic evaluation into their research projects. We are also currently involved in a number of cost-effectiveness analyses alongside clinical trials in different therapeutic areas.

In addition, we are expanding our training services to cover emerging fields in health outcomes research and health technology assessment, such as health services evaluation and diagnostic test accuracy research. With these initiatives in place, we hope to equip local researchers to meet the future demand for knowledge on patient outcomes and value-added health services.

Outcomes research has altered the culture of clinical practice by providing evidence about benefits and risks of healthcare services. It is the key to understanding the quality of care we are achieving and to identifying the deficiencies for further improvement.
OUR EPIDEMIOLOGY TEAM

From left to right: Dr Nurun Nisa de Souza, Dr Yoko Wong, Dr Shi Luming (HOD), Dr Charles Zheng
BUSINESS OPERATIONS SERVICES COMPRIZE

- Customised study proposals that meet trial objectives of partners
- Contract and budget administration services
- Effective communication between internal departments and external stakeholders

The Business Operations department often represents SCRI in reaching out to collaborators to share SCRI’s expertise.

The team supports our partners in the planning of their studies and budgeting processes by understanding clearly the collaborators’ requirements, and offering customised project proposals. As the coordinator between internal and external stakeholders, Business Operations also advises on the proposed workflows based on collaborators’ needs and requirements.

Effective coordination and communication is key in managing expectations of stakeholders. By reaching out to partners, the team works closely with them to ensure that SCRI’s proposed services not only meet partners’ needs but also fit their proposed budgets and finalised contracts.

For partners applying for research grants to fund studies, the team is also equipped with the facility to assess operational needs and propose budgets required for grant submissions.

From left to right:
Cristin Chua, Damien Hong (HOD), Alexa Shee, Jolyn Chuah
PROJECT MANAGEMENT SERVICES COMPRIZE

- Planning and organisation, monitoring and control of clinical research projects from study feasibility to close-out
- Protocol preparation and implementation
- Study budget preparation
- Oversight for protocol compliance, adherence to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guideline and standard operating procedures
- Study progress reporting
- Management and review of timelines, budget and deliverables
- Primary contact point throughout study

Good communication is vital. We know that the key to a successful project is in identifying study requirements and addressing the needs, concerns and expectations of the stakeholders in planning and executing the project.

At SCRI, we support the sponsor and Principal Investigator (PI) so they can focus on what really matters, patient care. By managing the set-up, running and closing of a clinical trial, project managers ease the workload of the study team. We enable sponsors and PIs to make sound decisions by overseeing communication with internal and external stakeholders, obtaining regulatory requirements and study updates, and presenting these as digestible reports.

SCRI’s Project Management expertise provides critical project oversight from project planning to study close-out, ensuring effective communication with stakeholders and maintaining project stability.

The team at Project Management realises benchmarks of clinical study excellence via protocol development, feasibility assessment and site evaluation. The department also works closely with stakeholders for the development of study guides like the Monitoring Plan and Study Operations Manual, on top of regularly reviewing budget and timelines to identify potential overruns.

Successful clinical research is a complex combination of multiple strengths. The project manager has a pivotal role in guiding study teams to work together towards common goals, overcome cultural variances and optimise work processes.

The team is committed to supporting clinical research excellence for better treatments for our patients. We seek to have all our project managers certified as Project Management Professionals (PMP), developing thought leadership and expertise in managing multi-national, multi-centre, investigator-initiated trials. Establishing a central database to consolidate our project knowledge and data over the decades will also ensure strength in business continuity.

In 2017, we will explore possibilities of outsourcing project management services and manpower to PIs which will further support them in site management and collaboration processes. The department will also seek to further showcase our expertise in managing multi-country, multi-cluster trials by expanding our network of investigators and therapeutic areas to encompass trials of medical devices.
OUR PROJECT MANAGEMENT TEAM

From left to right: Ho Shuet Han, Dr Cao Yang, Dr Gao Hong (HOD), Dr Li Xinhua, Wendy Zhao

Not in picture: Ivanus Manopo, Liew Wei Ming
The predecessor of the Project Management department was the clinical project coordination department first formed under CTERU in 1996. In 2006, the department evolved to include project management and monitoring. In 2013, the department formally formed two independent arms to further focus on their own areas of expertise: Project Management and Research Monitoring.

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**Project Challenges**

**Contract negotiation between multiple parties**

Review and negotiate contracts to coordinate agreement across all parties for terms and conditions.

**Numerous local and overseas vendors**

Coordinate three vendors across four countries (France, United States of America, United Kingdom and Singapore) to overcome challenges of different time zones, cultures and languages.

**Stringent timeline**

Motivate the study team to achieve targeted milestones on time; ensuring that timely study data is available for each safety review meeting with different disciplines.

**Quick amendments within short time-frame**

With five protocol amendments within eight months, experienced coordination across teams ensure that stakeholders impacted by changes are notified and necessary adjustments made within the project timeline.

**Non-standard invoices from multiple vendors**

Review and standardise invoice requirements.
OUR PROJECT MANAGERS

Clinic investigators understand that running a clinical trial is a complicated activity. Not having enough manpower to execute trial operations is also a real-world problem. To overcome these challenges, we optimise our experience in the field, working in hand with investigators to explore different ways of running the trial and to optimise trial resources. In sharing best practices, we are also able to align the study with the strategic goals of SCRI to improve clinical research on a national level.

Sponsors may be less familiar with the complexities of the start-up and operational processes and the time required in a big, multiple-centre study. The actual impact on other stakeholders, timelines and budget are areas we explain carefully to sponsors. We believe that our overall liaison helps all parties to appreciate the overall timeline, study deliveries and budget for a smoother study execution.
RESEARCH INFORMATICS

The complexity, size and cost of clinical trials have increased tremendously in the last decade. Clinical trials can be daunting to process without the aid of technology and tools, given the immense amount of data and coordination required in a clinical trial and the diverse study elements of different therapeutic areas.

SCRI's Research Informatics team provides support and expertise with expedient information technology to clinical research operations while managing operational costs in trials. Set up in 2008 with the objective of increasing productivity with strategic and cost-effective utilisation of technology, we were one of the earliest institutes to adopt the REDCap system.

As innovation is key for progress in clinical research, the team constantly explores new expertise to enhance existing implementation methodologies of clinical research studies. An example of the team's innovation is the design and development of RAND (Randomisation and Drug Management system), a unique randomisation and investigational product (IP) management system.

RAND supports configurable study parameters and allows investigators to screen and randomise patients, besides managing and tracking the IP inventory throughout the entire study process. The system streamlines the clinical trial process, keeping coordination and management efforts lean.

We believe that with our support and collaboration, as more studies and institutes adopt and use the RAND system, we can achieve better operational efficiency in clinical research.
OUR RESEARCH INFORMATICS TEAM

From left to right: Lee Simun, Zheng Yiheng, Huang Kuanfu (HOD), Henry Chua, Huang Ruipeng
The Research Monitoring team takes part in both local and international clinical trials, and it is staffed by trained Clinical Research Associates (CRAs) with accreditation from the Association of Clinical Research Professionals. SCRI’s CRAs collaborate closely with internal study teams and external stakeholders, driving the production of quality research data for local and regional clinicians.

Our department has diverse experience in the provision of monitoring services for different therapeutic indications, including oncology, infectious disease, metabolic disease and cardiology. Our CRAs are trained to ensure that trials are conducted, recorded and reported in accordance with protocol, SCRI SOPs, GCP and the applicable regulatory and IRB/IEC requirements.

Our CRAs undergo certification examinations by the Association of Clinical Research Professionals (ACRP) as part of their career progression. Their continual training ensures constant development of their technical knowledge and monitoring proficiency ahead of an evolving clinical trial landscape.

CRAs train investigation site personnel to meet study requirements and also conduct regular site monitoring visits to enhance operational efficiency and consistency of the projects at hand. Our CRAs’ expertise has taken them to countries ranging from Brunei, Hong Kong, Malaysia, Mongolia, Myanmar, New Zealand, Thailand, Philippines, South Korea, Taiwan and Saudi Arabia.

The team understands that building rapport with site collaborators is vital to efficiently resolve site issues together. Communication is key so that timely delivery of project plans and milestones are maintained while adapting to guidelines, regulatory requirements, working culture and environment variances.

On-site monitoring visits by CRAs ensure that the rights and well-being of trial patients are protected. This is achieved via verification of trial patient data as well as examination of quality compliance to GCP, regulatory requirements, SOP and the approved protocol.
OUR RESEARCH MONITORING TEAM

From left to right: Ng Siok Ting, Khoo Wei Zhi, Kelvin Ang, Janice Ng (HOD), Tan Choon Ping, Tan Siew Hoon, Lim Hui Qing

Not in picture: Chong Wan Ling
DATA MANAGEMENT SERVICES COMPRIS

- Creation and design of Case Report Forms (CRF) based on requirements of clinical trial protocol
- Design and development of study database
- Design and writing of data validation programmes for complex clinical data checks
- Development of CRF Completion Guidelines
- Data cleaning and query management to ensure integrity and accuracy of study data
- Training of study site personnel in data entry skills to ensure quality of study data
- Clinical Data Management System (CDMS) known as Oracle Clinical (OC), with a Remote Data Capture (RDC) application that allows data to be recorded directly at study sites
- Medical coding such as dictionary coding to enable classification of medical events and medications under the rules of established dictionaries (e.g. MedDRA and WHO Drug Dictionary)
- Use of business analytics and intelligence software called SAS Enterprise Guide for reporting of comprehensive data matrices

Specialised skills in Data Management are a rarity in Singapore’s clinical research scene.

To adequately support internal and external stakeholders in clinical research, SCRI’s Data Management team offers system training and skilful planning to ensure the integrity of data during a study.

Efficiency and intuitive usage of data management systems are also important towards streamlining the data gathering process, and the team strives to support this via development of electronic Case Report Forms (CRF) and project guides such as the RDC Users’ Self Help Guide. Validated international dictionaries such as the MedDRA and WHO Drug Dictionary are utilised to standardise medical terminology and drug names used in a study database.

When in place, these measures help to ensure a common language and stability throughout a study. Besides driving productivity at study sites, site staff can invest more time with study subjects instead of keying large quantity of information into the database.

To ensure that study data is thoroughly assessed, a comprehensive data management plan and study data matrices reports for principal investigators and project managers can be generated by the Data Management team.

The team utilises the Oracle Clinical system to manage clinical studies and systemise the keying of information into databases. For added focus during collection of data variables for analysis, user guides such as the CRF Completion Guidelines can be established.

It is important to sustain a pool of talents in the furtherance of clinical research excellence for the future. In light of this, the department has an ongoing partnership with Nanyang Polytechnic to provide internship programmes and introduce youths to a fulfilling Data Management career path in clinical research.
OUR DATA MANAGEMENT TEAM

From left to right: Doreen Leow, Amalia Hernandez, Su Jie, Ng Xuanhui (HOD), Lee Shu Ling
PHARMACOVIGILANCE SERVICES COMPRISE

• Review of all Serious Adverse Events (SAEs) in a study, and performance of safety analysis
• Processing of individual cases and assessment of investigational products
• Safety reporting to regulatory authorities and other stakeholders
• Provision of round-the-clock safety coverage

SCRI’s Pharmacovigilance team plays an essential role in product development, specifically providing safety support to investigator-initiated trials in order to achieve their full potential to provide quality healthcare.

The Pharmacovigilance team designs trial-specific SAE forms and safety monitoring plans which establish the safe use of investigational products, reduce risks and increase benefits for patients.

In collaboration with principal investigators of a study, the Pharmacovigilance team creates a centralised database to capture and monitor SAEs while ensuring timely identification of events that qualify for expedited reporting if necessary. The team also communicates closely with all site and study teams to provide medical support, consultation on SAE reporting, as well as training for SAE reporting, processes and timeline.

Other key services by the Pharmacovigilance team include performing SAE reviews and queries, coordinating with the investigational site to assemble SAE report packages, and carrying out SAE reconciliation. The team is trained in managing the complexities of multi-national and multi-centre trials, such as language and culture barriers, to meet the requirements of international pharmacovigilance regulations.

The Pharmacovigilance team safeguards patient safety standards for drugs and medical devices. It delivers the expertise of moving a new drug or device from conception to marketing stages while keeping headcount lean in today’s multifaceted clinical trials.

From left to right: Dr Gao Hong (HOD), Swetha Gangishetty
QUALITY ASSURANCE SERVICES COMPRIS

• Performing clinical audits to evaluate trial conduct and compliance of the trial to (1) protocol, (2) the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guideline, (3) applicable requirements of the regulatory authority and Institutional Review Board/Independent Ethic Committee (IRB/IEC) and (4) sponsor’s and SCRI’s standard operating procedures (SOPs).

• Conducting pre-audit/pre-inspection preparation for site personnel and clinical operations staff, and providing on-site support activities during audits and inspections.

• Training of site and clinical operations staff to meet requirements of audits from the institution, sponsor or health authority inspections.

• Providing GCP consultation and guidance to stakeholders.

• Fulfilling of QA services for external clients i.e. conducting on-site audit and inspection preparation.

The Quality Assurance department works closely with sponsors and local regulatory authorities for inspections and audits of clinical trials and their sites, ensuring that clinical studies are conducted with compliance to approved protocols, guidelines and regulations.

With the ability to provide quality management services for clients, including conduct of on-site GCP audits, the department builds quality into clinical trials by establishing internal SOP processes, while keeping project stakeholders abreast of evolving regulatory requirements.

For the purpose of human subject protection and study data quality, the department highlights the importance of research compliance and builds awareness of auditing requirements and procedures. Safeguarding the effectiveness and relevance of quality management activities is key. The Quality Assurance team keeps up with the evolving regulatory climate for clinical trials involving drugs and medical devices to ensure that its processes and procedures adapt to changing guidelines.

Quality Assurance is fundamental to establishing the merits in the delivery of SCRI’s core services, ensuring protection of human study subjects and reliable data returns. Building quality by design can help ensure that all aspects of the trial are operationally feasible with reduced complexity, thereby improving the efficiency and quality of the trial.

With the introduction of the new integrated addendum to ICH E6(R1) of the GCP Guideline, there is increased focus on quality management systems using a risk-based approach. The Quality Assurance team is exploring the potential of a quality management system that can be applied throughout all stages of the trial process so as to enhance efficiency and operational feasibility of investigator-initiated trials.
While its global clinical research networks provide an important platform for research breakthroughs, SCRI helps Singapore to enhance clinical trial efficiency.
CLINICAL RESEARCH NETWORKS AND MANAGEMENT

CLINICAL RESEARCH NETWORKS (CRN)

ASIA-PACIFIC HEPATOCELLULAR CARCINOMA (AHCC) TRIALS GROUP
The Asia-Pacific Hepatocellular Carcinoma (AHCC) Trials Group is a collaborative research group formed in 1997 by clinicians from major medical centres in the Asia-Pacific region. The mission of the AHCC network is to conduct preventive and therapeutic trials in Hepatocellular Carcinoma (HCC), carry out translational research in this field and develop training and educational programs pertaining to HCC.

FAMILY MEDICINE RESEARCH NETWORK (FMRN)
The Family Medicine Research Network (FMRN) is a practice-based research network formed in 2010. The FMRN seeks patient-centred clinical research and new information that will translate into better healthcare outcomes for patients. FMRN strives to answer important clinical questions relevant to disease prevention, early detection, treatment and long-term disease management.

METABOLIC RESEARCH NETWORK
The Metabolic Research Network (MRN) was established in late 2010. The purpose of the MRN is to: provide and support scientific leadership representation for the investigation of metabolic disease entities; provide a platform to support improved efficiency of the conduct of clinical trials through collaborative patient recruitment to competitive timelines; support research activities and aspire to be the source of expert knowledge and policy inputs in the metabolic disease domain.

PAN-ASIAN RESUSCITATION OUTCOMES STUDY (PAROS) CLINICAL RESEARCH NETWORK (CRN)
The PAROS CRN is a collaborative research group formed in 2010 by dedicated Pre-hospital and Emergency Care (PEC) providers conducting PEC research in the Asia-Pacific region. PAROS CRN endeavours to improve outcomes from PEC across the Asia-Pacific region through the creation of a platform to support and stimulate research into effective strategies to improve survival in PEC.

NEW CRNS IN 2016

ASIAN THORACIC ONCOLOGY RESEARCH GROUP (ATORG)
The Asian Thoracic Oncology Research Group (ATORG) was formed in 2016 with the vision of becoming a central coordinating platform for multicentre clinical trials and translational research for thoracic malignancies in the Asia-Pacific region.

The latest advances in medical science have led doctors and scientists to recognise that lung cancer is diverse and made up of many molecular subsets. Work has begun to identify these sub-populations of patients so that collaborative trials can be initiated to investigate new medicine to benefit patients.

ASIAN LIVER TRANSPLANTATION NETWORK (ALTN)
The Asian Liver Transplantation Network (ALTN) was established in late 2016, comprising prominent medical practitioners across Asia skilled in liver transplantation. The network focuses on the indications, outcomes and adherence of liver transplantation in Asia.

Through the pioneering work led by Starzl in the United States and Calne in the United Kingdom, liver transplantation has become the standard of care for patients with end-stage liver diseases and acute liver failure. It is widely acknowledged that differences exist between Western and Asian patients; both in terms of etiology for transplantation and genetic predisposition for conditions such as new onset diabetes after transplantation (NODAT).
Asian-centric research and outcomes are thus needed; and efforts to encourage multi-centre Asian collaborations required.

ALTN was set up with the vision to become a strategic network of key opinion leaders in liver transplantation from Asia. ALTN provides a platform for regular exchanges to facilitate best clinical practice and conduct multi-centre studies and clinical trials. The Network is working on filling clinical and research gaps in liver transplantation and to establish an Asian Liver Transplant Registry.

CLINICAL RESEARCH NETWORKS AND MANAGEMENT
SCRI’s CRN department was set up in 2010 to provide infrastructure for high-quality clinical research, collaborating with clinicians in the development of specific diseases, or practice-focused Clinical Research Networks (CRNs).

Each investigator-owned network consists of members from different research institutes and hospitals and creates an alliance of clinical research sites. With a CRN partnership, an entity gains access to a large and efficient network, driving results for expedited site identification and study start-up.

SCRI is unique in the Asia-Pacific region for network development. By providing the necessary frameworks to link investigators with research interests in the same disease arena, SCRI supports an environment conducive for efficient and effective conduct of clinical research.
RESEARCH NETWORK WORKSHOPS

Two training sessions were conducted by SCRI’s PAROS CRN in 2016 to help Emergency Medical Services (EMS) leaders and healthcare policymakers improve cardiac arrest survival within their communities.

PAROS RESUSCITATION ACADEMY WORKSHOP

29 SEPTEMBER - 1 OCTOBER 2016

Academia, Singapore

In collaboration with the Singapore Ministry of Health (MOH), Singapore Civil Defence Force (SCDF), SingHealth and Unit for Pre-hospital Emergency Care (UPEC), SCRI’s Pan-Asia Resuscitation Outcome Study (PAROS) CRN held its first Resuscitation Academy Workshop in Singapore from 29 September to 1 October 2016.

The Resuscitation Academy workshop was a three-day course designed to help EMS leaders and healthcare policy makers improve cardiac arrest survival in their communities. The workshop faculty included local specialists and overseas experts from Seattle, USA, who participated in the didactic lectures, demonstrations and practical sessions. Seattle faculty and PAROS members also visited the SCDF Headquarters to better understand the Singapore EMS system.

PAROS DISPATCHER TRAINING COURSE IN THAILAND

14 - 15 DECEMBER 2016

Rajavithi Hospital, Bangkok, Thailand

Together with the Department of Emergency Medicine and Narenthorn EMS Center at Rajavithi Hospital, Bangkok, Thailand, SCRI’s PAROS CRN conducted Thailand’s first Dispatcher Training Course from 14 to 15 December 2016.

The two-day Dispatcher Training Course was supported by research funding from Laerdal Foundation and attended by emergency physicians, emergency nurses, paramedics, and emergency medical dispatchers. The aim of the course was to provide dispatchers with recommended guidelines to deliver effective emergency instructions, including cardiopulmonary resuscitation (CPR) instructions, to callers over the telephone prior to EMS arrival.
The Clinical Trials Implementation Committee (CTIC) was set up in 2014 to enhance the efficiency of clinical trials conducted in Singapore, with SCRI as a key member of the committee. Together with research and clinical trial directors from the public healthcare institutions and other key stakeholders, SCRI works as part of CTIC to oversee the implementation of strategic initiatives based on recommendations by the preceding Clinical Trial Workgroup. The CTIC’s secretariat is jointly staffed by NMRC and SCRI.

As a key member of CTIC, SCRI’s responsibilities include:

• Encouraging the use of the Master Clinical Trial Agreement (MCTA)
• Assisting public healthcare clusters with queries regarding the MCTA
• Improving ethics review timelines
• Developing the National Clinical Trial Dashboard to track and measure the performance and efficiency of clinical trials
• Drawing up incentives for clinicians and public healthcare institutions to carry out clinical trials
• Developing and implementing training schemes and career framework for Clinical Research Coordinators (CRCs)
• Managing and coordinating National Clinical Trial Insurance implementation, negotiation, and submission, as well as renewing of policies for the public healthcare clusters

SCRI continues to implement strategic initiatives identified by CTIC, such as legal services for commercial trials in Singapore’s public healthcare institutions.

Provision of ad-hoc legal vetting services, as required by public healthcare clusters, continues to be available at SCRI today.

**KEY CTIC EVENTS IN 2016**

• Updating of agreement templates and assisting in National Clinical Trial Insurance renewal for public healthcare clusters
• Working with public healthcare clusters on the funding allocation for 100 Clinical Research Coordinators to the clusters
STRATEGIC ALLIANCE AND RESEARCH DEVELOPMENT

NATIONAL TRAINING PROGRAMMES AND CAREER DEVELOPMENT FOR CLINICAL RESEARCH COORDINATORS

To successfully conduct clinical trials, Principal Investigators (PIs) need the support of skilled and experienced Clinical Research Coordinators (CRCs) to help manage the research operations.

To further enhance career and training opportunities for CRCs, the Ministry of Health (MOH) has tasked SCRI with the spearheading of the national manpower development initiative for CRCs. Over the next five years, Strategic Alliance and Research Development (SARD) will work with the healthcare clusters to establish a core group of CRCs within the public healthcare institutions.

This initiative also includes designing a series of national training programmes for CRCs. To prepare for this, SCRI met with a wide pool of workforce development experts and potential clinical research training partners to benchmark existing CRC competencies and identify gaps in knowledge and skills.

To ensure that the learning and development needs of CRCs are met, SCRI will strive to improve CRCs’ access to quality, industry-relevant training. These efforts will support the advancement of Singapore’s research capabilities in meeting the future demands of academic and commercial clinical trials.
OUR NATIONAL CLINICAL TRIAL COORDINATION TEAM

From left to right: Patricia Tay (CRN), Surinder Kaur (CTIC), Damien Hong (COO), Caryn Goh (CTIC), Jobyna Ho (SARD)
SCRI spearheads the planning and delivery of training programmes for clinical research personnel to develop clinical research capability in Singapore and the region.
SUPPORTING DEPARTMENTS

OUR HUMAN RESOURCES TEAM & EXECUTIVE SECRETARY

From left to right: Christina Ng (HR), Rebecca Leong (Executive Secretary), Michelle Chan (HR)

Not in picture: Peter Tan (HOD, HR)

OUR FINANCE TEAM

From left to right: Kathy F. Reandlar, Au Wing Hong (HOD), Cherrylou Azuela, Jennifer Teo
HUMAN RESOURCES & TALENT DEVELOPMENT
The Human Resources & Talent Development department is in charge of talent acquisition, talent engagement, compensation & benefits, as well as career development & training.

EXECUTIVE SECRETARY
The Executive Secretary supports the CEO, CSO and COO.

FINANCE
The Finance department is in charge of clinical trial accounting, NMRC grant management, corporate treasury & financial management, taxation and statutory reporting.

CORPORATE AFFAIRS
The Corporate Affairs department is in charge of internal & external corporate communications, media partnerships, social media engagement, corporate branding & marketing, event management, business continuity planning, facility management & renovation, as well as office administration.

OUR CORPORATE AFFAIRS TEAM

From left to right: Ida Roziana Osman, Lisa Tan (HOD)
SCRI staff let their hair down at the aptly-themed dinner party “Garden by the Peak” on top of Mount Faber on 4 March 2016.

The combination of the hilltop’s relaxing ambience, scrumptious buffet spread and a line-up of lively music performances by SCRI’s very own staff was irresistible. Everyone got on their feet, dancing to the beat and the breathtaking view of the sunset from Mount Faber’s peak.

The evening’s highlight was the “Best-Dressed Contest” that had staff showcasing their creativity in fashion. The enthusiastic teamwork of the staff more than made up for the limited resources forming the floral “couture” outfits as their colourful eclecticism had both models and designers in stitches. The night ended with a Bingo game which saw 16 lucky winners taking home prizes.
13 May 2016 saw SCRI’s CEO Update and Staff Team-Building Day taking place at the Orchid Country Club. Dr Teoh opened the day with a presentation where he shared the company’s corporate performance and key strategies for the following year with staff. Following the CEO update, guest speaker Dr Christopher Cheok from the Institute of Mental Health delivered a talk entitled “Happy Employees and Happy Employers – Achieving Happiness at the Workplace”. After the informative session, SCRI staff took on the Archery Team Challenge for some light-hearted friendly rivalry while learning the sport together.

To commemorate Singapore’s 51st birthday, SCRI held a “Lorong” (corridor) competition. Staff members decorated their respective lorongs in creative ways that best represented what Singapore meant to them. The competition was tough. The teams’ enthusiastic efforts impressed the judges with their creative flair in working with recycled materials to produce unique decorations.
SCRI’s Chief Scientific Officer, Associate Professor Edwin Chan Shih-Yen, became the first person from SCRI to receive a Long Service medal at the Singapore National Day Awards (NDA) on 9 November 2016. The Long Service Medal, or Pingat Bakti Setia, was instituted in 1962 and is awarded to persons of irreproachable character who have served for at least 25 years.

The NDA distinguishes individuals of merit and service to Singapore and the session in 2016 saw a total of 436 officers from the public healthcare family being recognised for their service. The ceremony was graced by Minister for Health, Gan Kim Yong, who presented the Commendation, Efficiency and Long Service Medals to the recipients at the NDA Investiture.
EDUCATIONAL SPONSORSHIPS

To manage the development of SCRI staff, the organisation has launched an initiative to support individuals with a keen interest to achieve professional growth through further studies.

Four of SCRI’s talents took on further scholastic endeavours in 2016 with SCRI sponsorship, a testament to SCRI’s commitment to supporting staff in their professional development.

The programme included residential modules at two prestigious universities: Nanyang Technological University, Singapore (17 - 28 October 2016) and University of California, Berkeley (6 - 17 March 2017). This programme addressed key concerns such as: Developing Strategic Capabilities and Asian Leadership, Leadership Accelerator and Innovation & Entrepreneurship.

The BNAMP gave me the knowledge and skills to realise my individual and SCRI’s potential from the rich curriculum at world-class varsities such as the Nanyang Business School in Singapore and the Haas School of Business at the University of California. I was inspired to attend this management programme as this programme attracts outstanding participants from Asia, Europe, Africa, United States and the Middle East who boast a proven track record in senior management positions and reflect myriad backgrounds, sectors and nationalities. I was taught by one of the region’s most experienced business faculties and will definitely benefit from the strong network of global universities and learning institutions.

I hope to contribute to SCRI through my learning from the latest in management best practices from case studies and seminars with business leaders, as well as the highly interactive learning environment with a global peer group from this program. As an aspiring young leader, this program has provided real relevance to the challenges faced by senior managers at work. By actively participating in the program, I gained better insight and perspective on the ways to respond to the complex and changing business world, thus becoming a better manager and corporate strategist.

Janice Ng
Head, Research Monitoring
Benefitted from the Berkley-Nanyang Advanced Management Program (BNAMP)
Health economic evaluations are increasingly being conducted within clinical studies. The topic is becoming an important part of the overall assessment of new medical interventions throughout the world. In Singapore, health economic research and health technology assessment are gaining more attention, as their findings provide guidance on how best to allocate limited resources (e.g. healthcare budgets) to health technologies (e.g. drugs, surgical interventions or medical devices etc.).

I have great interest in learning more about cost-effectiveness analysis (CEA) for clinical trials, as it plays a particularly important role in health economics evaluation with its direct estimation of economic and clinical impact.

Although my involvement in research projects allows me to learn on the job, I would like to achieve a higher level of competency by building a firm foundation. This first-year course provided me with the basic principles and tools of health economics, and enabled me to better understand SCRI projects from an economic perspective.

University of York is a well-known university for education and research in health economics and their courses are of high requirement and standard. I chose economic evaluation of health technology assessment as my field of study as it is a very important topic in clinical research. Scarce resources mean that very often, resource allocation have to be weighed according to both clinical and economic concerns.

My course of study is conducted by distance learning which requires strong self-discipline and motivation. The overall experience is great as my reading materials were written by excellent researchers, tutor support is substantial and discussion within the class is comprehensive. Studying part-time with a full-time job requires commitment and sacrifice of leisure time but I am glad that I made the choice to do the course. After finishing the first year of the course, I was awarded a postgraduate certificate. I am now in the second year of study to pursue a postgraduate diploma. My goal is to continue the study, pursue a master’s degree, and produce more good work with SCRI teammates.
I believe that it is important to develop skills related to my career growth and I aim to remain competitive, relevant and employable in light of changing industry needs. I am undertaking this course as I wanted to obtain a holistic view of the world of business. The course provides a sound grounding with core themes in business, marketing, communications and research. The practical sessions have taught me essential people management skills and organisational teamwork which are crucial to my job. The theoretical part of the course sharpened my thinking process and developed key transferable skills that would aid me in my professional progression upon graduation.

Part-time study is intense, stressful and requires great discipline. However, it is possible to achieve a healthy work-family-study balance via good planning. I do face several challenges while balancing my roles as a working mum, an employee and a student, but I managed to implement routines, plan each day in advance and multi-task. To overcome the conflicting demands, I regularly update my Head of Department at Corporate Affairs to discuss class schedules and exam periods in advance. This is especially crucial when planning major projects such as the Annual Report and the Scientific Symposium. It has been a rich, learning experience that has helped me to develop skills not only in terms of technical knowledge, but also in time management to better balance multiple workloads with tight deadlines.
SEMINARS, CONFERENCES AND WORKSHOPS

COCHRANE ADVANCED SYSTEMATIC REVIEW AND META-ANALYSIS WORKSHOP
26 - 27 FEBRUARY 2016

Following our 26th successful Cochrane Basic Workshop on Systematic Reviews last year, SCRI conducted the first Advanced Systematic Review and Meta-Analysis Workshop in February 2016. This was the first of its kind in the region to cater to clinical and public health researchers, healthcare professionals and policymakers who wanted to move beyond systematic reviewing of randomised control trials (RCT) to non-randomised controlled trials of interventions (NCRT).

Participants gained advanced knowledge in literature search and reference management, design and analysis of NCRT, advanced literature searching risk of bias appraisal and meta-analysis of NCRT. The workshop provided a range of interactive presentations, small-group discussions, and hands-on computer exercises. About 20 participants from various public institutions attended the workshop. Speakers of the workshop included SCRI’s Associate Professor Edwin Chan, Dr Shi Luming, Dr Fahad Siddiqui, Dr Nisa De Souza, Dr Dianne Bautista and Dr Charles Zheng.

ASIAN TRANSLATIONAL RESEARCH CENTER WORKSHOP
1 MARCH 2016

On 1 March 2016, SCRI was invited by the Japan Agency of Science and Development and Translational Research Institute, an Academic Research Organisation (ARO), to attend the Asian Translational Research Centre Workshop held at the Toranomon Hills Forum, Japan.

Our Chief Operating Officer (COO), Mr Damien Hong, was one of the speakers at the workshop. He shared the best practices of the development of clinical research operations in Asia.

The workshop was attended by all Japanese AROs and also other organisations from Korea, Taiwan and Singapore.
SCRI IN-HOUSE META-ANALYSIS WORKSHOP WITH OVERSEAS VISITING EXPERT, DR MICHAEL BORENSTEIN
3 MARCH 2016

Dr Michael Borenstein presented two workshops to our Biostatistics and Epidemiology Departments on 3 March 2016: Software for Meta-Analysis and Computer Power for Multi-Level Studies.

He introduced and demonstrated the computer programme, Comprehensive Meta-Analysis (CMA), using it to perform a simple meta-analysis, assess the impact of moderators using subgroup-analysis and the impact of moderators using meta-regression.

Dr Borenstein also demonstrated computer programme CRT-Power. The software can estimate the intraclass correlation coefficient (ICC) at every level and work with a range of ICCs to find the most cost-effective design, taking into account the ICC and the cost at each level as well as any constraints. CRT-Power is also able to create plots that clearly show the trade-off among various options (i.e. power as a function of unit and cost), and reports that document all of these assumptions.

The workshop served to enhance the skills and capabilities of SCRI staff in performing meta-analysis. Participants were introduced to user-friendly tools for sample size calculation, especially for clustered randomised trials which will be beneficial for future studies.

SCRI-CSU ADVANCED CLINICAL TRIAL WORKSHOP – MANAGING LARGE INVESTIGATOR-INITIATED TRIALS
1 APRIL 2016

On 1 April 2016, SCRI conducted an Advanced Clinical Trial Workshop in collaboration with the National University Health System (NUHS) Clinician Scientist Unit (CSU) for the third consecutive year.

This one-day practical workshop was aimed at helping experienced investigators manage their Investigator-Initiated Trials (IITs). Participants rotated through three practical sessions to discuss with SCRI Key Faculty about issues such as project management, recruitment strategies, study monitoring and data analysis.

Collated feedback indicated that over 90 percent of the participants rated this workshop as "Good" or "Excellent". SCRI was pleased to partner CSU in conducting this one-day workshop which ensured that participants will be better equipped to plan and execute their projects.
ENDNOTE WORKSHOP
6 MAY 2016

On 6 May 2016, the Epidemiology department held a one-day in-house Endnote Workshop for Epidemiology and Biostatistics staff, highlighting the capabilities of the reference management software popular amongst researchers and students. The aim of this workshop was to enable participants to organise and cite references in their research manuscripts more accurately and effectively.

The workshop, delivered by Dr Fahad Siddiqui and Dr Nisa de Souza, encompassed short lectures and hands-on sessions on topics including how to formulate a focused research question, doing a search of medical literature, importing search results into and citing references from Endnote. Our participants found the activities very useful and looked forward to applying their skills in their work.

BASIC COCHRANE WORKSHOP + SPECIAL TOPIC ON DIAGNOSTIC TEST ACCURACY STUDIES
25 - 27 MAY 2016

In collaboration with Cochrane Singapore, SCRI Epidemiology and Biostatistics Departments conducted our 27th two-day workshop on Basic Cochrane Systematic Reviews of Interventional Studies and a one-day special topic workshop on Systematic Reviews of Diagnostics Test Accuracy (DTA) studies.

The speakers from SCRI were Chief Scientific Officer, Associate Professor Edwin Chan; Head, Epidemiology, Dr Shi Luming; Dr Fahad Siddiqui; Dr Nisa De Souza; Dr Dianne Bautista and Dr Charles Zheng.

The participants from various institutions and professions who attended the workshop found the interactive presentations, small-group discussions and hands-on computer exercises throughout the three-day workshop greatly beneficial.

The special topic workshop on DTA is a first for the region and was based on guidelines from the “Cochrane Handbook for Diagnostic Test Accuracy Reviews”. It was designed for clinical and public health researchers, healthcare professionals and policymakers who are interested in understanding key issues in the design and conduct of reviews of DTA.
**JOINT ALLIANCE DUKE-NUS EDUCATION (JADE)**

**31 MAY 2016**

Duke-NUS and Janssen Asia Pacific launched the JADE (Joint Alliance Duke-NUS Education) programme on 31 May 2016 to address the competency and development needs of industry Medical Affairs personnel. JADE, a joint educational initiative, is an online certificate programme specialising in Medical Affairs. It offers targeted training to help Medical Affairs respond quickly and strategically to the ever-changing industry and regulatory trends.

Our SCRI staff, CSO, Associate Professor Edwin Chan; CEO, Associate Professor Teoh Yee Leong; Head of Biostatistics, Mr Mihir Gandhi; Dr Nisa de Souza and Dr Pryseley Assam, contributed to the programme by utilising their expertise to develop the relevant content for various modules in the course.

Information regarding the course and sign-up links can be found on their website: https://nus.edu/2shR8Zy

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**INTERNATIONAL CONFERENCE ON TRADITIONAL CHINESE MEDICINE GUIDELINES & STANDARDS**

**17 - 19 JUNE 2016**

Associate Professor Edwin Chan was invited to deliver a lecture at the 1st International Conference on Traditional Chinese Medicine Guidelines & Standards in Guangzhou, China on 19 June 2016.

This conference was organised by the Chinese GRADE centre, Guidelines International Network Asia, World TCM Academic Association, Chinese TCM Academic Association, Guangdong TCM standards technical committee and Gansu EBM Practice Research Institute. The conference was also supported by the WHO Traditional and Complementary Medicine group, Guangdong TCM society, as well as Guangdong TCM and Western Medicine society.

The topic of the lecture was the inadequacies of tools currently used for quantifying evidence, and to propose a superior approach based on the likelihood paradigm.

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**COCHRANE WORKSHOP: SYSTEMATIC REVIEW & META-ANALYSIS**

**21 - 22 JULY 2016**

Our SCRI team delivered our 28th basic workshop on Cochrane Reviews on 21 and 22 July 2016 at the National University of Singapore (NUS) to teach participants more about the systematic review process. This workshop was jointly presented by SCRI, Cochrane Singapore, the Duke-NUS Medical School and the National University Health System (NUHS) Medical Publication Support Unit.

The two-day workshop covered key topics such as how to develop focused questions using the PICO method, how to perform effective literature search, assess risk of bias in studies, conduct meta-analysis using Review Manager, manage study heterogeneity and interpret the results. The content was delivered through talks, group activities and computer lab sessions to ensure that participants had a firm grasp of the concepts being presented at the workshop.
Associate Professor Teoh Yee Leong was invited as one of the guest speakers to share his experience and expertise at the first workshop organised by the newly formed College of Clinician Scientists, Academy of Medicine. Participants of the workshop included clinician scientists and industry stakeholders.

Associate Professor Teoh shared with the audience some of the current investigator-initiated trials supported by SCRI and why these trials were important to our patients. At the workshop, Associate Professor Teoh also explained why investigator-initiated trials would remain an important component of the landscape of clinical trials in Singapore.

Dr Dianne Bautista, Senior Biostatistician at SCRI, facilitated a basic workshop on “Choosing the Best Instrument for My Research” and an advanced workshop on “Validating My Instrument for Research” on 19 August 2016 at Duke-NUS Medical School.

The workshops focused on the search for, and the decision-making involved in, the selection of an appropriate instrument to measure outcomes in research studies based on practical considerations and scientific criteria. It also covered considerations involved in the decision to modify an existing instrument, the level of validation required and an overview of the methodology for validating or qualifying the modified instrument. The well-attended workshops were a joint partnership between AM•EI, AMRI and SCRI. They were attended by about 30 healthcare researchers.
SCRI held its 2nd Annual Clinical Research Symposium on 1 September 2016 at Stamford Ballroom, Raffles City Convention Centre.

The opening keynote address was made by Professor David Machin, the first director of CTERU, SCRI’s predecessor, who spoke on the Evolution of Trial Programmes for Singapore. Following this, the morning plenary session was helmed by keynote speakers Professor Alex Matter and Professor Pierce Chow.

It was a fruitful event with both external speakers (Professor David Machin, Professor Alex Matter, Professor Pierce Chow, Associate Professor Tan Say Beng and Dr Senthil Sockalingam) and internal speakers (Associate Professor Teoh Yee Leong, Associate Professor Edwin Chan, Dr Dianne Bautista, Dr Lu Qingshu, Dr Shi Luming, Mr Ivanus Manopo and Mr Peter Tan) sharing their insights into clinical research. Topics included Effectiveness of Pilot Studies, Adaptive Designs for Improving Efficiency of Clinical Trials, Increasing the Value of Clinical Trials with Cost-Effectiveness Analysis, Project Management in Investigator-Initiated Trials and CRC Career Development Pathway.
Alongside the 2nd Annual Clinical Research Symposium, the day also saw SCRI holding its 20th Anniversary Celebration Dinner. The dinner was presided over by Guest-of-Honour Senior Minister of State, Ministry of Communications and Information & Ministry of Health, Mr Chee Hong Tat. In celebration of SCRI’s 20 years in clinical research, 10 high-impact investigator-led clinical trials of SCRI’s healthcare partners were awarded.
INTERNATIONAL NETWORK OF RESEARCH MANAGEMENT SOCIETIES (INORMS) CONGRESS
11 - 15 SEPTEMBER 2016

SCRI participated in the sixth International Network of Research Management Societies (INORMS) Congress from 11 to 15 September 2016 in Melbourne, Australia.

The theme of the congress was Research Management in a Connected World and was aimed at those involved in research management and administration, from senior management through to those new to the profession.

More than 600 attendees from universities, research institutes, government agencies and the private and not-for-profit sectors shared their best practices and experiences. The congress facilitated connections on a personal, collegial and institutional level.

During this trip, SCRI met up with the Australasian Leukaemia & Lymphoma Group (ALLG). ALLG is a not-for-profit, collaborative clinical research group in Australia and New Zealand dedicated to finding new ways to treat blood cancers such as leukaemia, lymphoma, myeloma, myeloproliferative neoplasms and myelodysplastic syndromes.

RESEARCH PRESENTATION: EUROQOL RESEARCH FOUNDATION’S SCIENTIFIC PLENARY MEETING
15 - 16 SEPTEMBER 2016

Mr Mihir Gandhi, Head of Biostatistics, presented his research poster on “Chronic Disease Patients Valued EQ-5D-5L Health States Lower than the General Population” in the 33rd EuroQol Group Scientific Plenary Meeting on 15 September 2016 in Berlin, Germany.

Mr Mihir’s research study was funded by the EuroQol Research Foundation of the Netherlands. It recruited 525 chronic disease patients in Singapore and valued health states described by the EQ-5D-5L health status questionnaire. The study findings will be useful for performing cost-effectiveness analysis from the patients’ perspective.

4TH HEALTHCARE FAMILY STRATEGIC LEADERSHIP PROGRAMME
19 - 23 SEPTEMBER 2016

The Healthcare Family Strategic Leadership Programme (SLP) is the signature programme for public healthcare leaders. In 2016, SCRI’s Chief Scientific Officer, Associate Professor Edwin Chan, was a participant in this prestigious leadership programme.

Designed to develop a deeper understanding of policy imperatives and trade-offs, the programme brought together healthcare leaders from across the public healthcare sector, to examine emerging healthcare trends and challenges, and discuss future strategies and policy choices from a whole-of-government (WOG) perspective. The 4th SLP programme was conducted from 19 to 23 September 2016 and was fully funded by MOH.

SLP is developed for experienced leaders with the potential to assume key appointments in the public healthcare sector. Participants included Group Directors, Divisional Directors, Chiefs, Heads of Department, Director of Nursing (DN) and Head of Allied Health Professionals.
**SINGAPORE-STANFORD BIODESIGN (SSB) PROGRAM 2016**  
**21 SEPTEMBER 2016**

Dr Dianne Bautista, Senior Biostatistician, gave a talk on Clinical Trial Designs at the SSB Program on 21 September 2016. SSB Program is a national-level med-tech innovation training programme funded by A*STAR and Singapore Economic Development Board (EDB). Attended by 30 NUS, NTU and SMU graduate students, the discussion covered the Stanford biodesign process while offering Asian perspectives about med-tech development.

**NHG CLINICAL TRIAL COMMITTEE RETREAT**  
**28 SEPTEMBER 2016**

On 28 September 2016, Associate Professor Teoh Yee Leong was invited by the NHG Clinical Trial Committee to share his views on strategies to enhance clinical trials in the NHG group. Associate Professor Teoh shared with the group about on-going national initiatives to enhance clinical research efficiency in Singapore.

**DENGUE VACCINE RESEARCH MEETING**  
**11 OCTOBER 2016**

Associate Professor Teoh Yee Leong was invited to participate in Sanofi Pasteur’s Dengue Vaccine Research Expert Meeting held on 11 October 2016 at Carlton Hotel, Singapore. The meeting discussed the clinical trials conducted for the licensure of the new dengue vaccine (Dengvaxia) in Singapore which also involved local sites participating in global trials for the vaccine. Data on vaccine efficacy, immunogenicity, safety and reactogenicity were presented to the group for discussion.

**RESEARCH & QUALITY SYMPOSIUM**  
**14 OCTOBER 2016**

Associate Professor Teoh Yee Leong was invited by JurongHealth to be one of the keynote speakers for their inaugural Research and Quality Symposium held on 14 October 2016 at Ng Teng Fong Hospital. Associate Professor Teoh shared with the audience which included investigators, researchers and clinical research coordinators, tips on how busy investigators can conduct clinical trials. Associate Professor Teoh was also one of the judges for the Symposium’s oral presentation. An encouraging number of young researchers participated at the Symposium.

**IMMUNOSUPPRESSION IN LIVER TRANSPLANTATION - EXPERT PANEL MEETING**  
**16 OCTOBER 2016**

The SCRI Clinical Research Network team, together with Division of Gastroenterology and Hepatology NUHS, launched a new regional research network “Asian Liver Transplantation Network (ALTN)” on 16 October 2016. ALTN currently involves liver transplant specialists from Singapore, Hong Kong, Taiwan, Japan, South Korea, Philippines and Indonesia to facilitate future research on liver transplantation.

The first ALTN expert panel meeting was held on 16 October 2016 at NUHS Tower Block. The main aim of the meeting was to establish consensus guidelines on immunosuppression in liver transplantation for Asia. Associate Professor Teoh Yee Leong was invited to introduce the partnership between SCRI and ALTN, and Dr Charles Zheng, who supported the development of consensus guidelines, presented the methodology of the literature search.

**CORE SCIENTIFIC SYMPOSIUM 2016**  
**25 - 26 OCTOBER 2016**

Associate Professor Teoh Yee Leong, Dr Gao Hong, Dr Cao Yang, Ms Ng Siok Ting and Ms Lim Hui Qing attended the CoRE Scientific Symposium 2016 at Grand Copthorne Waterfront Hotel on 25 to 26 October 2016. The Conference discussed regulatory strategies, which included clinical trials, and promoted regulatory practice through learning from renowned global leaders on regulatory best practices to optimise impact on healthcare.
The Epidemiology department attended the 24th Cochrane Colloquium which was held in Seoul, South Korea, from 23 to 27 October 2016. The Colloquium is the annual scientific meeting of the global Cochrane community where ideas and the latest updates on Cochrane work are shared.

The team from the Epidemiology department actively participated in a wide range of plenary sessions, symposia and workshops offered at the Colloquium. They also presented a poster titled “A Systematic Review on Compliance of QUADAS-2 Tool Guidelines”, which was well-received by the participants.

The team planned to conduct more training workshops to introduce the new methodologies and research skills, and promote best practice of evidence synthesis, so as to benefit regional and local researchers and policy makers.

The Director of Cochrane Singapore, Associate Professor Edwin Chan, also attended the East Asia Cochrane Alliance Meeting in Seoul together with Dr Shi Luming and Dr Charles Zheng. The meeting discussed regional network and resource sharing, especially collaboration on training of systematic review trainers.

SCRI organised a Systematic Review and Meta-Analysis workshop with the Academic Medicine Research Institute (AMRI) on 10 November 2016 at Duke-NUS.

This one-day workshop provided essential guidance for the planning and conducting of systematic reviews. The workshop looked at how to formulate focused questions, perform effective literature search, assess risk of bias, manage heterogeneity in the evidence base, conduct a meta-analysis and understand the results.

Fifty-four participants from Ministry of Health and the Agency for Care Effectiveness (ACE), Duke-NUS, Nanyang Technological University (NTU), National University of Singapore (NUS), SingHealth and its affiliated institutes SERI, NCCS and Singapore General Hospital attended the workshop. The course and our speakers received highly positive feedback from the participants.

The material used in the workshop were developed by the SCRI Epidemiology team members of Cochrane Singapore for the courses conducted in Singapore. Associate Professor Edwin Chan also conducted a half-day training session for the Taiwanese workshop tutors, in addition to delivering a four-lecture half-day seminar series for the Taiwan Evidence-based Nursing Association and Taiwan Joanna-Briggs Collaborating Centre.


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IN SEARCH OF BETTER TREATMENTS FOR OUR PATIENTS