ALERTNESS SAFETY AND PRODUCTIVITY

An Australian Government Initiative

2014 ANNUAL REPORT

www.alertnesscrc.com

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EXECUTIVE SUMMARY

This is the first annual report of the CRC for Alertness, Safety and Productivity (the Alertness CRC) which was established following a successful bid for Commonwealth funding in the 15th round of the Cooperative Research Centres Program.

This initial year of activity for the Alertness CRC has brought a unique combination of academic and end user partners together and culminated in the development and commencement of four major platform projects. These platform projects underpin a well-defined mission to promote the prevention and control of sleep loss and sleep disorders and, to develop new tools and products for individuals and organisations to improve alertness, productivity and safety.

Poor alertness has widespread effects on core brain functions: reaction time, decision making, information processing and the ability to maintain attention. This impairment leads to preventable errors, accidents and injuries, especially in high risk environments. Almost 10,000 serious workplace injuries and more than 25,000 serious injuries from road crashes are caused by poor alertness each year. The cost to the Australian economy is substantial - over $5 billion a year in lost productivity and healthcare costs, and over $31 billion per year in the loss of healthy life.

Alertness CRC has brought together expert knowledge, state of the art technologies and effective translation pathways from industry, government and university sectors in a coordinated output-driven program of research and development. Technology companies, insurance industry, regulatory and policy agencies and safety sensitive employment sectors are all represented as end users. The participants have been actively engaged in a project planning process designed to drive organisational interests towards common goals through output driven research.

ACHIEVEMENTS

RESEARCH AND COLLABORATION

The development and execution of participant agreements established the detailed contractual framework for the collaboration process and the management of intellectual property. Subsequently, the Alertness CRC has implemented a milestone driven research plan around two major programs of research. There are three interrelated themes within both programs:

- Alertness Measurement and Prediction
  - Real time biomarkers and other measures of alertness
  - Biomedical technologies for sleep and alertness management
  - Data basing, modelling and data analysis
- Safety and Productivity Improvements
  - Dynamic scheduling systems
  - Smart lighting solutions
  - Personalised sleep health management

This theme based approach has been supported through the implementation of a collaborative research model with a transparent funding formula and process for approval.

Our emphasis on project team mechanisms for consensus and decision making as well as incentives for early stage impact in the field has resulted in the following significant achievements in the first year of our consortium approach to alertness management:

- The completion of targeted facilitation activities designed to support the development of the key platform projects including:
  - Identification and assessment of existing and emerging technologies for detecting and predicting alertness
  - Review and confirmation of candidate biomarkers for the assessment of the alertness state
  - Consensus around agreed definitions of alertness and standardised methodological approaches across the research activities of Alertness CRC
  - Feasibility assessment of novel biomarker measurement techniques
  - Interim analysis of existing experimental data to identify novel brain, blood, neurobehavioral and physiological measures as potential biomarkers of vulnerability to impairment
  - Detailed characterisation of lighting properties in the laboratory and operational settings and the design of prototype light sources
  - The design and implementation of a sophisticated relational database with protocols for access and analysis.
- The development of the four major platform projects that will drive the activities of the Alertness CRC over the next three years includes the following streams of activity:
- Laboratory-based development of systems and biomarkers to assess circadian, sleep and alertness states
- Modelling and software development for prediction of alertness and optimisation of scheduling and a data fusion system for the estimation, prediction and control of individual alertness dynamics
- Assessing individual vulnerability to shift work and integrated interventions for alertness management in the healthcare setting
- Sleep disorder phenotyping.

These projects provide large and complex data collection ‘engines’ and analysis capabilities for Alertness CRC that will underpin the ability of the consortium to achieve the proposed paradigm shift in approaches to alertness management. The development of the respective project agreements and the specific protocol detail that involves significant human clinical research is a major achievement for this consortium.

The Board of Alertness CRC Ltd would like to formally thank all participants and project team personnel for their extremely high level of engagement and intensive efforts to maximise the value of this consortium approach.

COMMERCIALISATION AND UTILISATION

The availability of background intellectual property (IP) and a range of in-kind contributions in the form of state of the art technologies in alertness management and related fields have presented significant opportunities for the Alertness CRC. The incorporation of this background IP and the existing technologies into the activities has greatly enhanced the likelihood of success and provided a range of predetermined deployment pathways for the expected outputs.

Whilst the research program is entering a critical and significant data collection phase, all project agreements have included identified early stage outputs that are now being incorporated into detailed utilisation plans.

To further encourage early stage impact, the board of Alertness CRC Ltd has established a ‘Deployment Fund’ within the budget. This is available to CRC participants to fund ‘activities with outputs that can be immediately deployed upon completion. The fund is designed to complement the four platform projects and allow participants to leverage specific alertness management opportunities via smaller, more targeted projects.

EDUCATION AND TRAINING

At an organisational level, the focus has been on creating structures and processes that facilitate output driven collaboration. At the project level the focus has been on building capacity within the research teams (including end user representatives) to maximise the value of the consortium approach via a well-managed project team structure.

During the first year a formal education committee was established to oversee the development of a comprehensive education, training and industry placement program.

A total of eight Project Leaders were appointed to manage the seven streams of activities in the four platform projects and the development and implementation of the database and data mining infrastructure. These Project Leaders were supported by the Program Leadership and the CRC Executive but were given significant responsibility around project development and implementation. With the initial focus on end user engagement and protocol development, project leaders led and participated in a number of CRC workshops and end user meetings throughout the year with a more formal program of training scheduled for year two. A further 4.5 postdoctoral positions have been incorporated into project agreements for year two.

A PhD recruitment program was initiated in collaboration with the academic partners of Alertness CRC The identification of specific PhD projects was a priority of the project planning process. A total of 24 PhD positions have been established and are expected to be filled by the third quarter of year two.

The Education Committee has also approved a Masters Entry program with a view to transition to PhD with recruitment commencing in 2015. In addition the Alertness CRC has been actively pursuing opportunities to provide industry based learning positions (stipends) for undergraduates from any Australian academic institution.

In addition to the numerous internal workshops and participant forums conducted during this critical planning phase, the Alertness CRC is actively supporting a post graduate course to be held at the annual scientific meeting of the Australasian Sleep Association in Perth in October 2014. The course: ‘Managing Alertness in Industry - Minimising Risk & Optimising Productivity’ will continue as an annual event.

AWARDS

- **Patricia Faulkner**, AO – Chair – Awarded the degree Doctor of Laws honoris causa by Monash University in September 2013.
- **Professor Ron Grunstein**, Program Leader – Appointed Distinguished Professor, Sydney Medical School, 2014
- **Professor Karen Reynolds,** Theme Leader – Named by Engineers Australia, for the second year running, as one of Australia’s ‘Top 100 Most Influential Engineers’, 2013.
- **Anthony Williams**, CEO - Recipient of the Australasian Sleep Association ‘Presidents Award’ in recognition of leadership in building research capacity and high impact research in the field of sleep, October 2013.

RISKS AND IMPEDIMENTS

The activities the Alertness CRC has embarked upon are cutting edge. A certain degree of risk is always involved in the development of ground breaking and innovative technologies. Ultimately, it is the research plan that will dictate the success of this consortium but it is the structure and processes within which these activities will be managed that facilitates genuine and effective collaboration between the participant organisations.

This first year of the Alertness CRC has focused primarily on finalising the structure and developing and presenting these processes to the consortium members. With participants ranging from large multinational organisations and government agencies to small and medium enterprises and academic institutions there was necessarily an extended period of negotiation with concurrent and critical project planning activities carried out.

With project activities commenced under a well-defined project team structure and with a comprehensive set of milestones and deliverables, the Alertness CRC's focus has turned to effective project management and utilisation planning.

END-USER ENVIRONMENT

Driving evidence based change in behaviour, work practices, policy and legislation as well as community responses to the 24/7 society can reduce the avoidable safety and productivity costs of the 'sleepiness epidemic'. The lack of accurate, reliable and easily-deployable alertness measurement and prediction tools; the non-personalised treatment and intervention approaches (one-size-fits-all) and the under supported regulatory and policy frameworks to tackle sleepiness-related harm, highlight the need for a unique mix of participant involvement in the Alertness CRC as well as the need to engage a range of stakeholders beyond the Alertness CRC consortium.

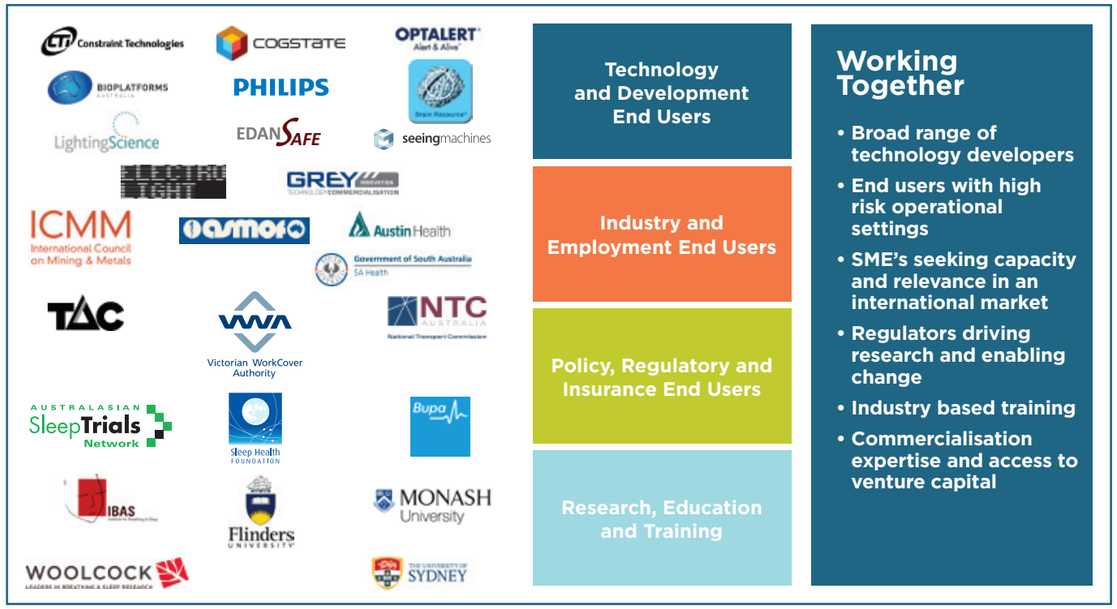
To achieve a paradigm shift and trigger a new era in alertness management, the Alertness CRC has established a consortium that includes:

- A broad range of technology developers
- End users with high risk operational settings
- SME's seeking capacity and relevance in an international market
- Regulators that want to drive research and enable change
- Commercialisation expertise and access to venture capital.

These participants provide a several levels of opportunity for strategic placements and cross sector capacity building. These opportunities will be continuously monitored and exploited through the formal project team process. This process ensures all participant interests are represented and communication is structured and transparent.

Whilst the focus is currently around the development of activities that align with the strategic priorities and deployment opportunities identified by CRC participants, the CRC has commenced the development of a broader stakeholder network in key operational settings. These will provide specific collaboration and deployment opportunities for CRC participants and a range of project outputs.

The major advantage of the end user configuration of the Alertness CRC is the availability of unique expertise; state of the art technologies; and, a significant pipeline of background IP that is being incorporated into the research and development activities. The Alertness CRC has developed a detailed and robust IP management structure that will be supported by comprehensive and early stage utilisation planning.



IMPACTS

The programs and projects of the Alertness CRC are interrelated and interconnected. They all focus on delivering comprehensive, integrated, state of the art outputs that are expected to trigger a paradigm shift in the approach to alertness management.

MEASUREMENT AND PREDICTION	SCHEDULING OF WORK AND SLEEP	SMART LIGHTING SOLUTIONS	PERSONALISED SLEEP HEALTH
Technologies and biomakers of alertness impairment (biochemical, physiological)	Personalised sleep-wake monitoring / scheduling device that provides tailored information on wake and sleep promoting interventions (e.g. caffeine, light, melatonin)	Software for portable devices to deliver light alerting countermeasures, and 'smart programmable LED lighting and systems	Measuring individual vulnerability to sleepiness and targeted management of sleep disorders
Optimising and combining technologies and biomakers for real-time portable alertness monitoring	Organisational rostering software based on state-of-the-art biological alertness models, task demands and operational factors	Light timing and use of different light colour strategies to adapt to shift work and jetlag	Individualised sleep and alertness monitoring devices, scheduling software and 'Apps'
Sophisticated mathematical modelling of sleep and wake to predict alertness		Software to facilitate customised lighting design	Customised lighting integrated with sleep, work and alertness assessment
Integrated platform to deliver systems and tools			
Education and advocacy to drive change			

Notwithstanding the comprehensive establishment phase that has just been completed and the value of those preliminary outputs to the research plan, the development of the four major platform projects and the integrated database represent the first major steps for the Alertness CRC. These activities are consistent with the proposed outputs, usage and impacts as described in the impact tool. Importantly, these platform projects and their discrete streams of activity will provide the systems and tools to ultimately provide:

- Financial savings for the community from reduced road accidents and reduced workplace accidents
- Roadside test and workplace fitness for duty monitoring technology for Australian SMEs to commercialise
- Clinical tools and database systems that the wider sleep treatment and sleep research sector will utilise
- Health system savings and productivity gains from fewer workplace accidents due to better scheduling
- Savings in industry from fewer workplace accidents/errors due to better lighting
- New scheduling solutions for Australian SMEs to commercialise.

In order to maximise the impact of the Alertness CRC outputs as they are developed and to engage with a broader stakeholder network, the Alertness CRC has commenced the development of a customised research translation model. The model is designed to engage with end user organisations with high risk, safety critical operational settings outside the current participant configuration. This model of engagement will provide a portal to CRC participants (collaboration) and improve alertness management capabilities. The model is a hybrid research / intervention model and is to be established in addition to the proposed research translation network of key end user 'intermediaries' such as peak bodies, industry bodies, unions, professional associations that will assist in the development and dissemination of the new guidelines.

RESEARCH

In this initial year of activity, the Alertness CRC has made significant progress towards its key objectives with a series of (nine) targeted facilitation projects that has resulted in the finalisation of four major platform projects that will provide the foundation for a new paradigm in the management of alertness in the community. These platform projects have been established in three key settings (laboratory, clinical and occupational) with a sophisticated data analysis capability supporting work across these populations. The activities are interrelated and are designed to provide the systems and tools to better measure and predict alertness state and trait and to incorporate these tools in scheduling, lighting and sleep health management interventions.

RESEARCH PROGRAM ONE - ALERTNESS MEASUREMENT AND PREDICTION

The objective of Program One is to develop and verify tools to measure current alertness levels accurately, predict the risk of future critical lapses, and intervene before poor alertness impairs productivity and safety. Monitoring alertness in practical settings using validated technologies and biomarkers will permit individualized alertness assessment and use of targeted countermeasures. This will be a significant step change compared to current approaches of relying on inadequate self reporting or the 'one size fits all' responses.

Theme 1.1 - Real-time Biomarkers and Other Measures of Alertness

Biomarkers are biological characteristics that can be objectively measured to provide information on changes in alertness and therefore risk of alertness failure. Other measures of alertness might include those that are based on neuro-behavioural performance, electrophysiological and cognitive markers, self reported outcomes, or established devices of alertness measurement. As the alertness state fluctuates due to circadian phase, time awake or chronic periods of restricted sleep, these measures should be sensitive to changes in the alertness state due to these factors. The objective is the identification of novel real time biomarkers and other alertness measures to assess the risk of poor alertness. To achieve this, the research team has developed a strategy that is designed to:

i. Empirically validate a blood based tool of circadian assessment to be then incorporated into operational settings;

ii. Initiate a biomarker discovery program using proteomics, metabolomics and antibody based detection methods to identify small molecule and protein markers of alertness;

iii. Determine whether a novel nanoparticle based detector can measure biomarkers from saliva or sweat; and

iv. Develop an alertness test battery.

Note that the test battery will include biomarkers and other measures of alertness, including established electrophysiological and cognitive markers, and new "next generation" alertness measures developed in conjunction with Theme 1.2. The test battery will be used across the research programs for alertness assessment, including facilitating the validation of interventions such as smart light solutions and scheduling. It will also inform personalised sleep medicine programs aimed at phenotyping risk of alertness failure.

After initial laboratory testing of alertness outcomes, field-based validation will move to operational environments within the Alertness CRC participant group. The biomarkers and alertness measures identified in this program of work will then be incorporated into devices for testing fitness for duty and roadside alertness tests as well as personalised alertness and management devices.

A major output, and key to the identification and development of biomarkers of alertness to be used across the Alertness CRC program, is verified definitions and criteria for defining and evaluating alertness, sleepiness, fatigue, and performance. The aim of this initial activity was to provide clear conceptual and operational definitions of alertness and impairment terms. To establish consensus around the definitions and measurement of each term, a range of end users and experts in the field were consulted via a structured consultation process. A systematic review of the current scientific literature was also conducted and the findings are now being used to aid in the evaluation of existing tools to measure alertness and to conduct gap analyses around alertness state measurement capabilities. Testing and verification of the definitions and related improvements in measurement capabilities will continue.

Theme 1.2 Ð Biomedical Technologies for Sleep and Alertness Management

Based on both the integration of existing technologies and the development of new technologies the objective of this theme is to develop novel tools for measuring and predicting alertness and related quantities such as performance, sleepiness, fatigue, and personal sleep monitors. It will draw on measurement inputs from Theme 1.1; data analysis and modelling tools from Theme 1.3; and data from Program Two, and will reciprocate with new tools and devices.

Existing alertness detection systems have had limited impact and reach because each relies on a single "silver bullet" physiological measurement. This is too simplistic for real world settings and none has been systematically validated under complex, real world conditions.

The Alertness CRC is in the unique position of being able to bring together these separate technologies and integrate them, along with new measurements developed, into a comprehensive and accurate multimodal system for alertness detection.

Work has also commenced to investigate and develop new sensing and monitoring technologies, implement signal analysis methodologies to maximise the usefulness of the data being collected, and ultimately design new devices providing new and enhanced information on alertness and other related quantities. The first step in development of new devices is to have a comprehensive understanding of the current state-of-the-art. Initial activities have focused on objective identification and assessment of both existing and emerging technologies for detecting and predicting alertness.

Theme 1.3 Ð Data basing, Modelling, and Data Analysis

The initial activities associated with this theme centres on the storage of Alertness CRC and related data in forms that can be easily used and secondly, the development of an integrated suite of new methods to analyse these data and to model the physiological systems that generate them.

The core database is designed to archive data from all activities and serve as a repository for software and definitions developed within the Alertness CRC. It has easy to use interrogation features (thereby setting it apart from simple data stores), the ability to correlate multiple data types, and robust data pipelines that handle acquisition and processing of diverse data, subject confidentiality, quality control, IP, and access permissions. Protocols for the collection and storage of data have been established as platform project plans have been finalised. Implementation is continuing as complex procedures and acquisition processes are standardised across the CRC nodes.

In addition to the integrated database, Alertness CRC is developing new methods of signal analysis and data mining to extract patterns and significance from the data stored. Initial activities defined the scope for modelling and software development to outline feasibility and strategy going forward. This essential groundwork included:

- The identification and negotiation of access to pre-existing datasets that could be used for model optimisation
- Determination and implementation of model upgrades required for alertness prediction and scheduling optimization
- Definition of the key types of scheduling and optimization software.

This work is related to multiple CRC deliverables and will have a major role in supporting:

- A paradigm shift in workforce scheduling by advancing the knowledge on system disturbances during shift work and developing tools to optimize schedules
- Novel fitness-for-duty testing devices by providing new tools for prediction of alertness in given conditions
- Portable alertness testing devices and lighting countermeasures by developing model and software to predict alertness and effects of lighting.

RESEARCH PROGRAM TWO - SAFETY AND PRODUCTIVITY IMPROVEMENTS

Program Two is designed to demonstrate that alertness can be maximised at individual, workplace and community levels to deliver measureable improvements in safety and productivity. Systems and devices shown to improve alertness will have widespread applications, particularly in safety critical occupations such as healthcare and mining. This program is developing, testing and validating new tools and approaches to improve alertness.

Theme 2.1 Ð Dynamic Scheduling Systems

The objectives of this theme are concurrently being serviced by a number of activities across the Alertness CRC including the development of an evidence based framework for shift scheduling (initially in the healthcare setting) that will ultimately be utilised and tested in a variety of occupational groups. To establish and test this framework, an intensive set of activities that will facilitate comprehensive assessments of healthcare workers alertness state has commenced. These assessments will incorporate biomarkers and technologies from Themes 1.1 and 1.2 as they become available and objective measures of performance and safety (e.g. medical errors, adverse events, and injuries). Study populations include staff in the intensive care unit, wards, emergency room and operating theatre at the Austin Hospital and South Adelaide Local Health Network.

This project is critical to achieving the two key outputs under this theme:

(1) Prototype of a work/duty scheduling software system and scheduling guidelines for groups of employees; and

(2) Prototype of an individual-level scheduling system suitable for safety-critical occupational groups, with capacity to measure and predict alertness.

Activities include an intensive study of alertness, sleep, circadian rhythms and occupational performance and safety in intensive care unit workers at a major teaching hospital. This study will contribute to the development of algorithm(s) for identifying and predicting staff that are most vulnerable to alertness failure due to shift work; objective tools for monitoring alertness, and testing fitness for duty and driving safety, suitable for deployment through occupational health and safety programs.

This work also draws upon Theme 1.1's biomarker discovery and evaluation program, and Theme 1.3's modelling and data fusion outputs to provide a system capable of monitoring multiple physiological, cognitive and behavioural measures of alertness, sleep wake/activity rest history and light exposure (see Theme 2.2), in addition to operational/task demands and logistics.

Theme 2.2 Ð Smart Lighting Solutions

Light allows us to see but also has a number of 'non-visual' physiological effects including resetting our body clock and directly activating the brain to improve alertness and performance. Light thus has enormous potential as a safe, non -pharmacological countermeasure for improving alertness. This Theme tests the effectiveness of lighting countermeasures in a range of occupational and other settings – e.g., installation of blue-enriched light improves alertness and productivity in offices. Through the two platform projects in the laboratory and healthcare setting, we have commenced the process of quantifying the benefits of different lighting types in safety-critical occupations that will allow the integration of these findings into lighting and architectural design tools to promote widespread use of improvement in lighting countermeasures.

The objective is to develop 'smart' lighting systems that use combinations of light wavelength, intensity, timing and pattern to optimise the alerting and body clock-resetting effects of light. The advent of solid state lighting technologies means that such complex lighting can be mass-produced inexpensively. These units are easily programmable and permit individualised 'smart' lighting interventions that interact with alertness assessment tools. For example, the scheduling software (Theme 2.1) will be combined with a lighting system into an integrated device to provide the correct intensity, wavelength and pattern to optimise alertness in an individual shift worker.

Theme 2.3 - Personalised Sleep Health Management

This Theme is currently focusing on two highly prevalent sleep disorders that contribute to reduced productivity and safety – obstructive sleep apnea (OSA) and insomnia. These disorders are even more common in specific occupational groups – e.g., 45% of Australian truck drivers have OSA – and lead to a several-fold increased risk of occupational accidents and injuries and reduced productivity.

The objective of this set of activities is to develop new systems for efficient phenotyping of OSA and insomnia and a paradigm to determine the most effective treatment approach for each individual. These systems will be suitable for deployment in occupational and, more widely, into community clinical practice. This new approach will address the suboptimal 'one size fits all' treatment approach, which limits treatment effectiveness and may not be feasible in large-scale screening and treatment programs.

Current methods for diagnosing OSA and insomnia are not feasible on a large scale and have had limited impact. Furthermore, current methods cannot establish the causal mechanisms known to underlie these disorders. A further problem is that daytime neurobehavioral and alertness impairment, which is of greatest concern for driving and workplace safety, is highly variable between individuals. Around half of all OSA patients do not report sleepiness, and recent sleep deprivation "stress test" experiments suggest that around a third are highly resistant to alertness and performance problems, while others show vulnerability to task failure. These variable underlying causes and consequences of OSA and insomnia likely explain poor treatment tolerance and outcomes in many individuals. Current overly simplistic "one size fits all" methods for diagnosing and managing these disorders are therefore no longer appropriate and more strategic approaches are needed.

As this project includes intensive data collection, the standardisation of measures across sites is critical to the ability of the consortium to achieve the specified objectives. Extensive planning and preparatory activities were therefore required for protocol development and site standardisation, which have been the major foci of activities to date.

This theme of activity will be further serviced as the Alertness CRC develops and tests a protocol for screening for sleep disorders (i.e., OSA, insomnia) in occupational settings via the proposed healthcare platform project.

EDUCATION AND TRAINING

The establishment of the Alertness CRC Education Committee provides a formal framework within which to manage the education, training and industry placement program of the Alertness CRC.

The main role of the Education Committee is to provide oversight regarding the selection, training and interactions of students and post-doctoral awardees of the Alertness CRC. The Education Committee will also be responsible for non-PhD training opportunities such as industry internships for students and post-doctoral awardees originating from the academic nodes and varied academic attachments for individuals with a predominantly industry or other end user background. The Education Committee is responsible for monitoring progress and relevance to CRC (education) milestones.

Postdoctoral Training

Activities in this first year of the Alertness CRC focused on the development of the major platform projects. This involved the appointment of eight Project Leaders to manage the seven streams of activities in the four platform projects along with the development and implementation of the database and data mining infrastructure.

The appointment of postdoctoral awardees to the role of Project Leader has resulted in significant 'hands on" training in the collaborative process as the respective Project Leaders have driven the project agreement development with the support of site investigators, the Alertness CRC program leadership, the Alertness CRC Executive and the end user representatives. Project Leaders have been given significant responsibility and have actively participated in a series of end user consultation sessions and project planning workshops including regular research team meetings and formal (methodology) review sessions.

The achievements of the Project Leaders during this planning and setup phase of the Alertness CRC cannot be understated as they completed complex and interrelated research plans and incorporated them into formal project agreements which are now being implemented.

An additional 4.5 postdoctoral positions have been incorporated into project agreements for year two of the Alertness CRC along with a formal program of capacity building (short) courses around commercialisation and project management.

PhD Program

The extensive and relatively lengthy negotiations around the participant agreements and the extended period of project planning due to the complex nature of the four platform projects being developed has created some delay in finalising PhD project scope. Notwithstanding this delay, a PhD recruitment program was initiated in collaboration with the academic partners of the Alertness CRC in the second quarter of year one with over 15 applications received. The identification of specific PhD projects was a major priority of the project planning process and whilst no PhD's were appointed in the first year of operation, a total of 24 PhD positions have been established and are expected to be filled by the third quarter of year two.

Other Graduate and Post Graduate Training

The Education Committee recently approving a Masters Entry Program as a precursor to PhD appointments. A formal recruitment process for the Masters' Program will commence in Year two. The Alertness CRC is also actively seeking placements from non-participating academic institutions for industry based learning candidates. These candidates will be engaged on discrete projects that include high levels of industry engagement and training and support in commercialisation and project management.

Table 1: Education – Approved Postdoctoral and PhD Funding 2014/15

PROJECT OR CENTRE ACTIVITY	POSTDOCTORAL FELLOWS	PHD CANDIDATES (FULL)	PHD CANDIDATES (TOP UP STIPEND)
Laboratory-based development of systems and biomarkers to assess circadian, sleep and alertness states.	1.1	3	1
Modelling and software development for prediction of alertness and optimisation of scheduling and a data fusion system for the estimation, prediction and control of individual alertness dynamics.	2.2		5
Assessing individual vulnerability to shift work and integrated interventions for alertness management in the healthcare setting.	4	6	
Sleep disorder phenotyping.	4.2	8	
Design and implementation of a sophisticated relational database with protocols for access and analysis.	1	1	
Total	**12.5 (8)**	**18**	**6**

* Bracketed numbers indicate positions filled in 2013/14

SME engagement

The Alertness CRC has engaged SMEs in the consortium as participants (both essential and other). While in some cases the ability of SME's to contribute significant resources to the research activities is limited, the consortium members recognise the innovative capacity and opportunities that SME engagement brings.

The research and development activities of the Alertness CRC are based on discrete project teams and agreements however the projects themselves are highly interrelated and in many cases involve common project parties. The larger participants have been eager to support the involvement of SMEs in project teams and the Alertness CRC has already seen some examples of the larger multinational participants establishing direct and separate lines of communication with Australian based SMEs about specific collaboration opportunities.

The existing SME partners have been heavily involved in both the development of the major platform projects of Alertness CRC and in bringing a range of potential opportunities to the table for discussion and analysis. In several cases, SMEs feature heavily in the project utilisation plans.

The Deployment Fund established by the Alertness CRC Board provides a separate line of funding which is currently linked to specific project proposals that, if approved and implemented, could provide early stage impact in the field for several SME's within the consortium.

RESULTS

Utilisation and commercialisation

While Alertness CRC activities in this first year have focused on the development of the four major platform projects, the process and level of participant engagement during this period is designed to ensure the utilisation and commercialisation goals are fulfilled in accordance with the Commonwealth milestones.

In Program One, the development of biomarkers and better tools to measure and monitor alertness state and trait are critical to the ability of Program Two to develop sophisticated interventions to improve safety and productivity. These tools and measurement capabilities developed in Program One will also be available for development as standalone products with a number of CRC participants expected to participate in the deployment process.

A key activity that has commenced in the Alertness CRC that will greatly enhance the utilisation potential is the design and proposed implementation of a formal research translation 'engagement model' for non-participant industry based organisations that operate in high risk, safety critical settings. The Alertness CRC is currently working with a large multinational organisation to develop a model for engagement outside the participant structure. This model is being developed as a hybrid research/intervention model where the value of the CRC effort can be immediately translated into unique operational settings with a view to ongoing measurement, intervention and monitoring. This alertness management package will provide a genuine and effective research translation pathway and will allow participant organisations from Alertness CRC to immediately engage beyond the consortium boundaries. It will also allow key aspects of the platform project activity to be repeated or customised in different operational settings.

The existing links to the wider sleep research and sleep disorder treatment sectors (both in Australia and internationally) will ensure early access and adoption of database and diagnostic tools. The involvement of the Australasian Sleep Trials Network and the ability to roll out standardised tools will facilitate this early adoption.

In Program Two, a very clear pathway for the deployment of advances in scheduling has been established with key participant involvement and utilisation plans well advanced. This participant involvement and the expected timeline for model based improvements in group and individual scheduling provides early access to large occupational markets. In addition, the proposed research translation model will facilitate ongoing integration of these tools with a range of opportunities for deployment within and via participant organisations.

The utilisation of lighting design software and portable lighting devices will again be maximised via a number of pathways within the Alertness CRC participants and through the proposed research translation model in high risk, safety critical settings.

Intellectual property management

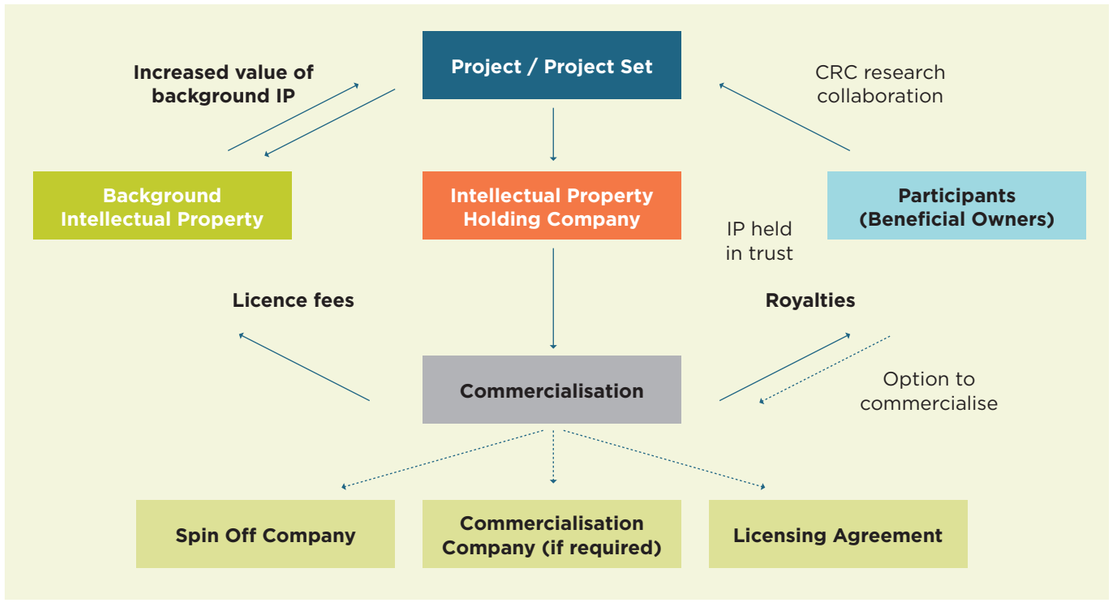
Whilst the Alertness CRC has yet to generate items of intellectual property (IP) from project or centre activities, there is a robust process in place to secure future IP and ensure that maximum benefits accrue to end-users, research providers and Australia.

Background IP made available by participants is registered and managed via the project agreements and utilisations plans. The utilisation plans are being developed at the earliest stage possible with an emphasis on predicting the value of IP and the appropriate licensing fee thresholds to avoid complex negotiations for access to background IP for utilisation.

IP generated by the Alertness CRC activities is the focus of the utilisation plans with a comprehensive process for determining the appropriate commercialisation pathway enshrined in the essential participants agreement. As they are developed, these utilisation plans include conditions that ensure the optimum strategy is supported by those organisations granted rights to commercialise/deploy.

Alertness CRC IP is to be legally held by an IP holding company (Alertness CRC Holdings Pty Ltd) on behalf of the beneficial owners (see Figure 1). The beneficial owners will be the essential participants of the Alertness CRC and ownership will be based on their proportional contributions to the projects or activities that generate the IP. Other participant project parties will be contractually entitled to an interest in the returns arising from the utilisation of Project IP, proportionate to its contributions to the Project.

Figure 1: Alertness CRC Intellectual Property Management Structure



With extensive student involvement in CRC activities and the need to ensure adherence to the 'National Principles of IP Management for Publicly Funded Research', the Alertness CRC has developed clear contractual terms around student ownership of IP; the rights to publish; the right to be examined ; and the right for participant organisations to utilise IP for non-commercial purposes.

The IP management structure of the Alertness CRC ensures that every effort is made to provide benefit for Australia and that the ownership is vested appropriately (including academic participant organisations). Board control and oversight and detailed utilisation plans ensure IP is protected and made available through licensing and appropriate accessibility arrangements.

Communications

During the 12 months of the CRC's establishment period, the internal communications strategy has focused on the consortium members and the development of the end user driven research program. The level of communication with all participant organisations has been extensive, regular and occurring at several levels. The negotiation of the participant agreements required not only legal and administrative input but a clear understanding of the opportunity and value proposition for all participants ranging from SMEs to large multinationals. A concurrent and intense period of research planning moved from involvement and review of the facilitation projects to the development of the four major platform projects where specific end user drive and commitment was critical to the finalisation of project agreements and budgets.

Internal communication has been managed through face to face meetings with all partners, as well as telephone conferences, personal email and broadcast emails to all researchers and/or all core participants.

The involvement of the Sleep Health Foundation (SHF) in the Alertness CRC presented a unique opportunity to develop an integrated communications and stakeholder relations strategy. In the first year of activities the Alertness CRC was invited to participate as a member of the SHF Business Council. This has provided formal access to a range of industry partners not directly involved in the Alertness CRC and an opportunity to leverage a well-established advocacy vehicle in the field to ensure that there is an effective mechanism to translate advances in alertness management to the broader sleep health stakeholders. In this initial period the SHF provided significant communications and stakeholder support and the integration of these activities are ongoing and will provide a sustainable advocacy vehicle for the consortium going forward.

RESOURCES

As a Cooperative Research Centre, the Alertness CRC has a well-defined mission to promote the prevention and control of sleep loss and sleep disorders and to develop new tools and products for individuals and organisations to improve alertness, productivity and safety.

In achieving these objectives, the CRC management company (Alertness CRC Ltd) has the opportunity to build a research and development facility that is efficient and effective, providing a unique opportunity for organisations / stakeholders in the field to add value to each other and produce deployable outputs.

To develop a successful and sustainable CRC, the first steps are the most critical. Structures and processes to drive the interests of all parties towards a common goal provide a good basis for output driven research. Having significant impact in alertness management is the primary goal.

Alertness, safety and productivity are negatively influenced by sleep loss, sleep disruption and shift work (circadian or body clock disruption), due to widespread effects on core brain functions such as reaction time, decision making, information processing and the ability to maintain attention.

The Alertness CRC is addressing the following five key challenges:

- The available tools to measure, monitor and manage the public safety risks posed by reduced alertness are currently inadequate
- Sleep loss affects different people in different ways
- There has been a failure to account for the variation between individuals when managing fatigue
- Effective strategies to improve alertness in the workplace and to help shift workers reduce the health and safety risks inherent in their work schedule are lacking or poorly integrated with other aspects of their lives
- There has been no evidence based program to determine the best way of informing the public, professions and regulatory groups about how to manage work schedules to optimise alertness.

Within each research program are three themes which provide the framework for the research, development, testing and marketing of individual products. Each theme is co-led by one end-user and one academic partner to ensure balance of high quality market-focused research and development. Cross-fertilisation among themes will be facilitated by having individual CRC members participate in multiple projects.

The Company, Alertness CRC Ltd is a not for profit company limited by guarantee. The objectives and obligations are clearly set out in the Company Constitution, and the Commonwealth and Essential Participants Agreement. Under this structure, the overall mission of the Company is to:

(a) Promote the prevention and control of sleep loss and sleep disorders in human beings and improve alertness, safety, productivity and health;

(b) Develop new tools and products for individuals and organisations to:

  (i) Relieve illness from and reduce the impact on alertness of sleep loss and sleep disorders;

  (ii) Advance public health, welfare and quality of life through improved sleep and alertness;

  (iii) Advance education in relation to sleep and alertness; and

  (iv) Protect the safety of the general public through improved sleep and alertness;

(c) Manage a cooperative research centre in Alertness, Safety and Productivity that pursues world class research and training;

(d) Ensure that the Participants with their differing disciplines and backgrounds will, through their participation in the Centre, add value to each other so that the performance of the Alertness CRC will be greater than that of each Participant acting independently;

(e) Increase the skills of persons already working in Alertness, Safety and Productivity and to train and equip new postgraduate and other students;

(f) Promote a managed and cooperative approach to research and education in alertness, safety and productivity so as to maximise the benefits from that research and education;

(g) Carry out education activities for students and for the professional development of persons working in alertness, safety and productivity;

(h) Promote the CRC Program Objectives; and

(i) Utilise the intellectual property created by the Centre to ensure that the maximum benefit accrues to Australia, including Australian industry, the Australian environment and the Australian economy generally.

The market place in which the Alertness CRC operates is extremely large and diverse in one sense and relatively compartmentalised in another. The sleep and circadian research community is well defined and regular peer review provides convenient tracking of the evidence base and research opportunities. However, the broader market place for the deployment of CRC outputs (i.e. alertness, safety and productivity improvements) is diverse, significant and presents a large range of potential collaborating organisations.

The business model of the Alertness CRC centres again on the flexibility to collaborate with the relevant partner organisations. Participants are encouraged to work with third parties where mutual interest/benefit exists and the project agreement process facilitates this wherever possible.

The Alertness CRC is developing a number of additional and formal networks outside the existing participant group to engage a broader range of stakeholders; monitor market conditions; identify opportunities for funding beyond the CRC program; and, bring additional expertise to project activities that identify such a need. When deployable outputs are created, the participant groups, project teams and the broader stakeholder network provide immediate pathways for commercialisation.

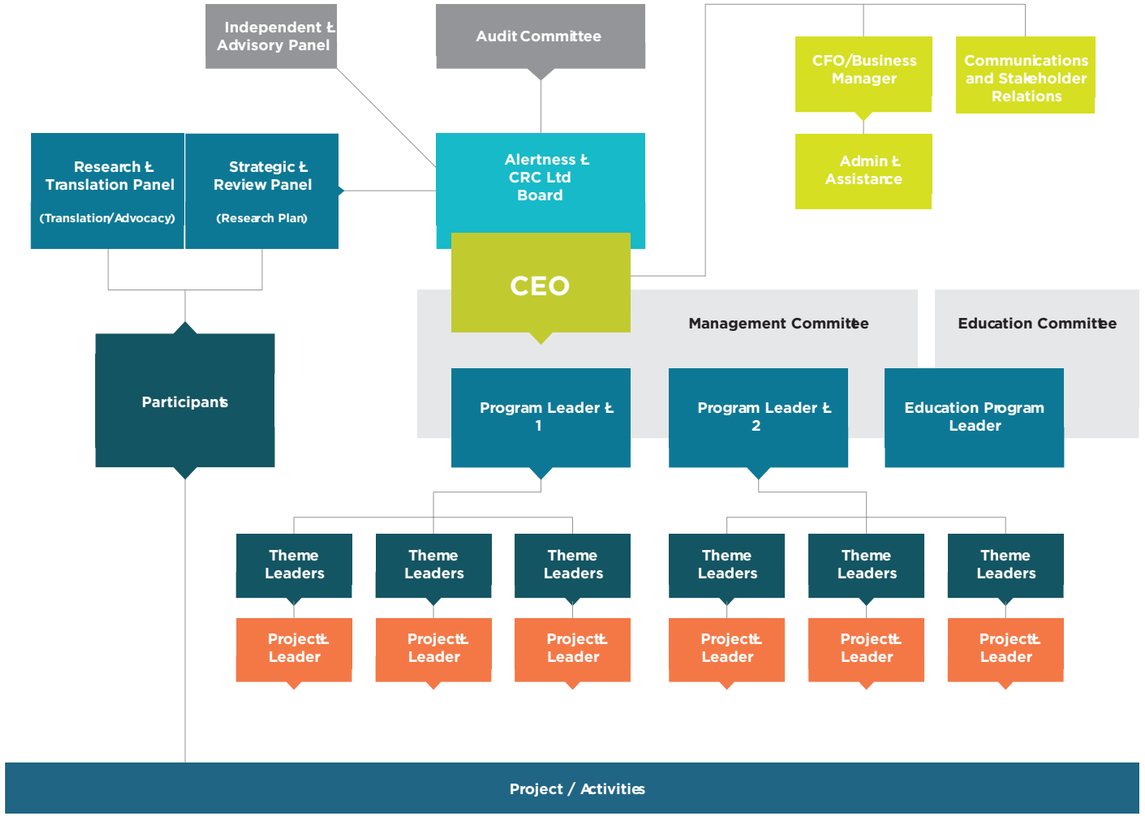
Governance

The CRC for Alertness, Safety and Productivity (Alertness CRC) was incorporated on 24 April 2013. The Company is a public company limited by guarantee. The Company is registered as a health promotion charity with the Australia Charities and Not-for-profits Commission (ACNC) since its inception. The Australia Tax Office (ATO) has provided its endorsement to Alertness CRC Ltd as a charitable institution to enjoy the following tax concessions from 24 April 2013:

1. Income Tax Exemption
2. GST Concessions
3. FBT Exemption

In addition, Alertness CRC is endorsed by ATO as a deductible gift recipient effective from 12 September 2014. Figure 2 below illustrates the organisational structure of the company and consortium.

Figure 2: CRC for Alertness, Safety and Productivity Organisational Structure



Alertness CRC Ltd is governed by a Board of Directors that is independent of all participant organisations. The board has a combined set of skills and experience that is well suited to the challenges and mission of the Alertness CRC (Table 2). Due to a delayed commencement date for the Alertness CRC, a total of three meetings of the Board of Directors have been held during the reporting period and these are listed in Table 3 along with records of attendance.

Table 2: Alertness CRC Board of Directors

NAME	ROLE	KEY SKILLS	INDEPENDENT/ ORGANISATION
Patricia Faulkner, AO	Chair	Patricia Faulkner, B.A. (Econ & Psych), Dip.Ed. M. Admin has been CEO of large and complex government departments and a Partner in a major advisory firm (KPMG). Her career has spanned the most senior levels of the public, private and the not for profit sectors. She now has an extensive portfolio of Board and advisory roles, both as Chairman and member.	Independent
Peter Maloney	Board Member	Peter Maloney, B.Comm. MBA, has wide experience as a business executive and company director, both in Australia and internationally, across a range of industries. He has been a director of various public and private companies since 2000. Peter was Chairman of Southern Health, the largest healthcare provider in Victoria 2003-2006.	Independent
Ian Farrar	Board Member	Ian Farrar, B.Comm. is an experienced company director who has chaired public, private and government organisations and is well versed in contemporary corporate governance issues. He is a skilled commercial manager with a strong track record of achievement in areas such as large scale asset utilisation, funds management and strategic asset allocation, financial management, insurance, information systems, statistical analyses, occupational health and rehabilitation, research management and organisational change.	Independent
Deena Shiff	Board Member	Deena Shiff, B.Sc. (Econ) Hons; B.A. (Law) Hons, has 15 years' experience as a non-executive director on both public and private sector Boards and experience in fostering emerging businesses. Deena served as a Group Managing Director at Telstra Corporation and was the founding CEO of Telstra's corporate venture capital arm. Prior to that, Deena was a Partner at King & Wood Mallesons, in house corporate counsel at Telstra and a senior executive and adviser on legal and social policy reforms for the Australian Government.	Independent
Anthony Williams	CEO and Board Member	Anthony Williams B. App. Sci., MPH has extensive experience and a proven track record in clinical research and business development. As a team leader with international, national and regional roles, Anthony has expertise in research management, financial modelling, corporate governance, intellectual property management and contract development.	Independent

Table 3: Alertness CRC Board of Director Meetings

Name	Number eligible to attend	Number attended
Patricia Faulkner, Chair	3	3
Deena Shiff	3	3
Ian Farrar	3	3
Peter Maloney	3	3
Anthony Williams	3	3

The structure includes an independent advisory panel that provides ad hoc advice and analysis to the Board as required. This advisory panel was not required during the reporting period but includes expertise in circadian biology, sleep medicine and occupational health and safety policy development.

Two participant panels have been established via the participants' agreements to provide consortium members with a mechanism to advise the board and monitor its performance in the context of the essential participants' agreement.

Strategic Review Panel

- Advises the Board on the project activities and research direction of the Centre
- Meets bi-annually in person or via telephone or video link
- Is chaired in any one Financial Year by a representative of the end user Essential Participant which has the largest cumulative annual cash contribution budgeted for the Financial Year which the meeting is held and who will report directly to the Board as required
- Includes one representative from each Participant which chooses to make an appointment
- Includes the CEO, Research Program Leaders and the Education and Training Unit Leader as ex-officio members.

Research Translation Panel

- Advises the Board on the research translation activities of the Centre
- Meets bi-annually in person or via telephone or video link
- Is co-chaired by representatives of the SHF and BUPA, until either party ceases to be an Essential Participant or the Board decides to replace either or both co-chairs at its discretion
- Is comprised of up to one representative from each Participant which chooses to make an appointment
- Includes the CEO, Research Program Leaders and the Education and Training Unit Leader as ex-officio members.

The operations of the Alertness CRC are managed by the CEO and Business Manager. Table 4 shows the key staff for the reporting period. Note the Alertness CRC has had several temporary Business Managers and some sessional assistance in the early stages of the reporting period.

Table 4: Alertness CRC Key Staff

Name	Organisation	Position/Role
Anthony Williams	Alertness CRC Ltd.	CEO
Kalpana Kao/Peter Gong	Alertness CRC Ltd	Business Manager
Helen Burdette	Sleep Health Foundation	Communications Manager
Professor Peter Robinson	University of Sydney	Program Leader
Professor Shantha Rajaratnam	Monash University	Program Leader
Professor Ron Grunstein	Woolcock Institute of Medical Research	Education Leader
Dr Clare Anderson	Monash University	Theme Leader
Professor Karen Reynolds	Flinders University	Theme Leader
Professor Sanjay Chawla	University of Sydney	Theme Leader
Dr Mark Howard	Institute of Breathing and Sleep	Theme Leader
Dr Steven Lockley	Monash University	Theme Leader
Professor Doug McEvoy	Flinders University	Theme Leader
Suzanne Ftouni	Monash University	Project Leader
Tracey Sletten	Monash University	Project Leader
Sveta Postnova	University of Sydney	Project Leader
Jong Won Kim	University of Sydney	Project Leader
Bryn Jeffries	University of Sydney	Project Leader
Chris Gordon	University of Sydney	Project Leader
Peter Catcheside	Flinders University	Project Leader
Andrew Vakulin	Flinders University	Project Leader

The Management Committee consists of the Program Leaders and the CEO and has met fortnightly during the reporting period to ensure direct communication between the executive and the research teams. A fortnightly meeting of the full program leadership has also assisted with efficient internal communications. These meetings are chaired by the Program Leaders in rotation with the CEO in attendance.

A fortnightly Project Leader meeting schedule has been established to assist with structural and operational issues around the implementation of project agreements. This meeting is chaired by the CEO or Business Manager and is attended by Project Leaders.

Participants

There were no changes to the participant configuration and it remains as per the Commonwealth Agreement as shown in Table 5.

Table 5: Alertness CRC Participants

Participant's Name	Participant type	ABN/ACN	Organisation type
Austin Health	Essential	96 237 388 063	State Government
Australian Sleep Trials Network	Other	88 002 198 905	Other
Australian Salaried Medical Officers Federation	Essential	56 536 563 722	Other
Bioplatforms Australia Limited	Essential	40 125 905 599	Other
Brain Resource Limited	Essential	24 094 069 682	Industry/ Private Sector
BUPA Foundation (Australia) Pty Ltd	Essential	67 113 817 637	Industry/ Private Sector
Cogstate Pty Ltd	Other	80 090 975 723	Industry/ Private Sector
Constraint Technologies International Pty Ltd	Essential	13 054 631 462	Industry/ Private Sector
EdanSafe Pty Ltd	Other	61 094 352 959	Industry/ Private Sector
Electrolight Pty Ltd	Other	93 288 579 088	Industry/ Private Sector
Grey Innovation	Other	14 083 304 214	Industry/ Private Sector
Institute for Breathing and Sleep	Essential	39 093 685 879	Other
International Council of Mining and Metals	Essential	UK based	Industry/ Private Sector
Lighting Sciences Group Cooperation	Essential	US based	Industry/ Private Sector
Monash University	Essential	12 337 614 012	University
National Transport Commission	Essential	67 890 861 578	Australian Government
Optalert	Other	79 121 747 591	Industry/ Private Sector
Respironics Inc - A Phillips Healthcare Company	Essential	24 008 445 743	Industry/ Private Sector
Seeing Machines Limited	Other	34 093 877 331	Industry/ Private Sector
Southern Adelaide Local Health Network	Essential	14 227 133 467	State Government
Flinders University	Essential	65 542 596 200	University
The Sleep Health Foundation	Essential	91 138 737 854	Other
Transport Accident Commission	Essential	22 033 947 623	State Government
The University of Sydney	Essential	15 211 513 464	University
Woolcock Institute of Medical Research Limited	Essential	88 002 198 905	Other
Worksafe Victoria	Essential	90 296 467 627	State Government

Financial Management

Alertness CRC has completed its first year of seven years funding period (2014-2020).

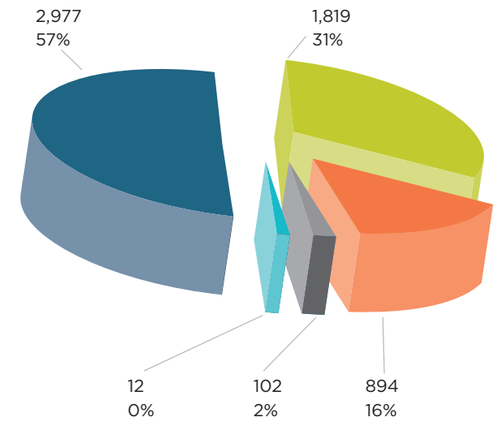
Total resources available including cash and contribution in-kind received during FY13/14 was $5,804K, as compared to $10,660K per plan. The majority of the shortfall was attributed to contribution in-kind, which formed 83% of the shortfall. Management anticipates these contributions in-kind will increase to the level per plan as the projects are being executed in FY14/15.

$894K was received from participants during the financial period, compared to a planned cash contribution of $1,754K due to delay in project start up. Subsequent to 30 June 14, 69% of the $860K shortfall has been collected.

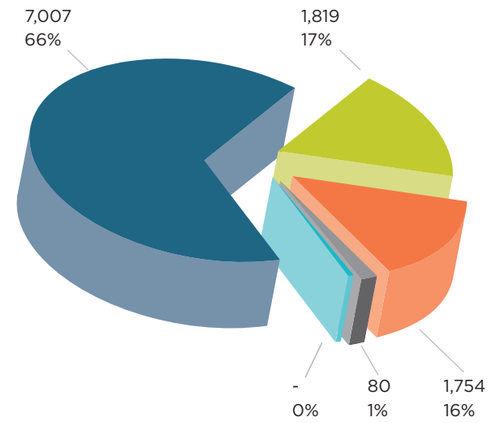
Alertness CRC has ended FY13/14 with a healthy financial position with surplus of $2.4mil to be carried forward to FY14/15 and utilised when projects are being executed as planned.

The financial statements of Alertness CRC have been independently audited by Pitcher Partners for submission to the ACNC and the Commonwealth CRC Program.

FY13/14 Resources Available ($'000)



FY13/14 Resource per Plan ($'000)



GLOSSARY

Actigraphy - provides measurement of the motion associated with rest and activity. In the case of sleep studies, a watch like device is attached to the wrist.

Antibody - a protein produced by the body's immune system when it detects harmful substances, called antigens.

Biomarker - short for biological marker, it is a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, disease or the effect of an intervention.

Circadian rhythms - are physical, mental and behavioural changes that follow a roughly 24-hour cycle, responding primarily to light and darkness in an organism's environment. They are found in most living things including animals and plants.

Co-morbid - a medical condition present at the same time as another one.

CPAP - Continuous Positive Airways Pressure Treatment for sleep apnea to keep the airways open.

Electrophysiological - the production of electrical phenomena, particularly in the nervous system, and their consequences in the living organism.

Homeostatic drive - the mechanisms of an organism or cell that maintain internal balance by adjusting its physiological processes.

Hyper arousal – the state or condition of muscular and emotional tension produced by hormones released during the fight-or-flight reaction.

Metabolomics - defined as the non-targeted detection and quantification of small molecules (metabolites) in biological materials (e.g. plasma, urine, tissue, plant and microbial extracts).

Obstructive sleep apnea - when the airway at the back of the mouth is repeatedly partly or completely blocked during sleep reducing or stopping breathing altogether. When oxygen levels fall, the sleeper wakes up briefly and starts breathing again.

Phenotype – The observable characteristics of a person in the context of specific trait, behaviour or susceptibility to a certain condition.

Proteomics – the study of proteins.

An Australian Government Initiative