Establishing Translational Research Pipelines for Smart Devices

Using EMG Analysis to validate the stages to technological maturation of a Manual Wheelchair lightweight sensing hand rim

1 Background:

The development of a translational research path has traditionally been a haphazard approach, filtering technologies so that the 'best of breed' may ultimately succeed.

The conversion ratio of brilliant ideas to useful devices remains suboptimal, as many 'fail to progress'. The reality of developing biotechnology transfer and Knowledge Transfer (KT) generally, is that the ability of multidisciplinary teams (MDT) to assimilate and then act upon information is becoming the rate limiting step for the building of complex projects.

The model proposed here considers both the biological aspects of Life Sciences (LS) and the establishment of Technology Readiness for its implementation.

2 Methods:

By offering a sustainable generic structure for the assimilation and transfer of technologies, at a rate supported by the individual teams, the potential is for standalone Web 2.0 enabled system components to be able to accommodate clinical research and governance needs.

The construction of a "signature", which reflects the current state of development, and thus the rate progress of translation, the development of the technologies, and potentially allows us to draw comparisons across different multidisciplinary environments, so as to ensure that adequate resources are allocated to assure their interoperability within agreed timescales.

Virtual Research Integration and Collaboration environment

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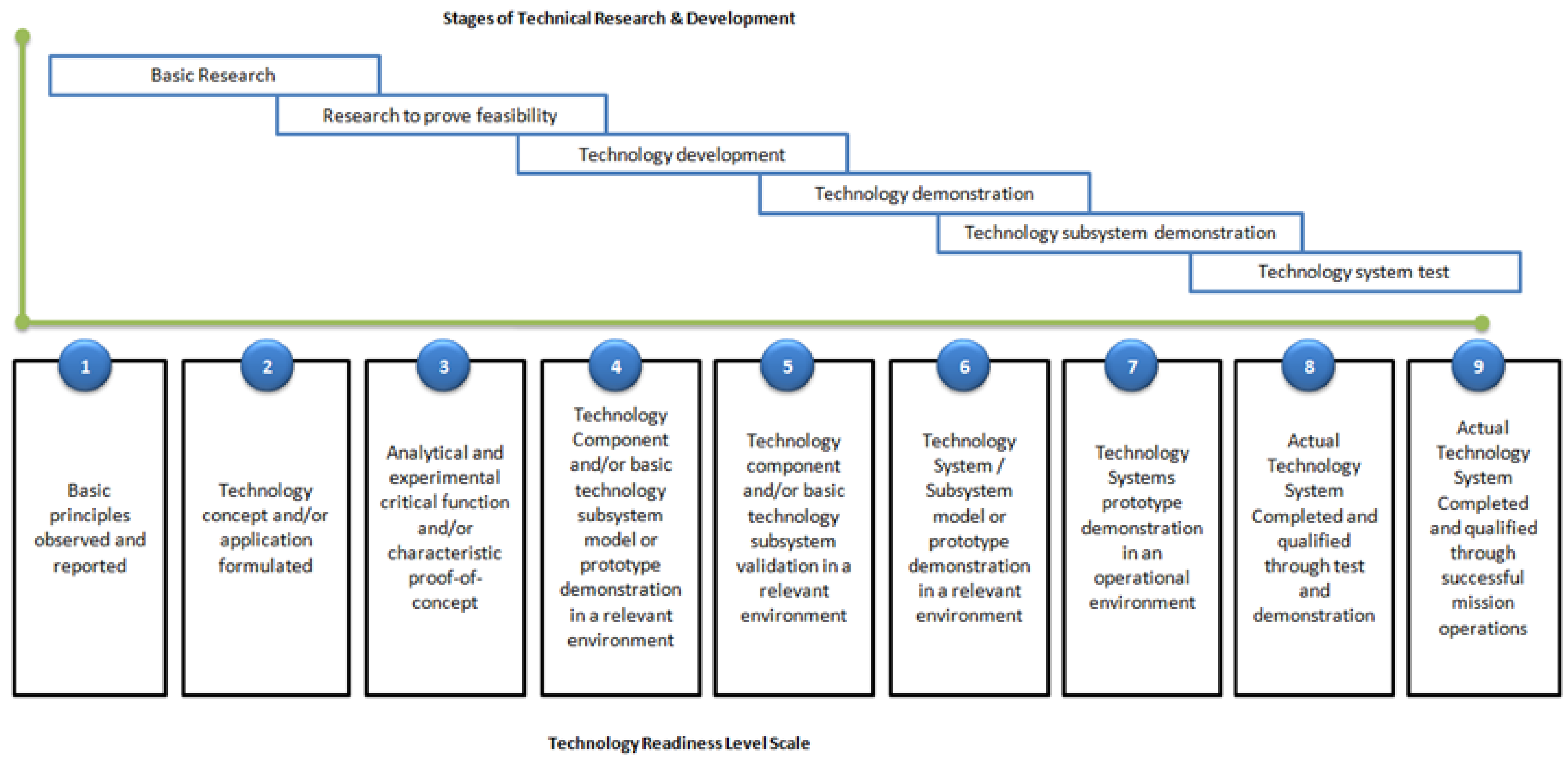
3 Results:



A case example applying this process to the development of the PowerWheel, a 'force sensing' lightweight hand rim for manual wheelchair allowed for the kinematic data to be compared with Electromyographic (EMG muscle patterning) data. This demonstrate that this strategic approach can be operationalized. By mapping the EMG signals from the basic science experiments through to clinical evaluation, the groundwork was completed for assuring rapid integration of approaches for the afferent arm of novel 'autosensing' FES technologies.

This integrates with work practices across disciplines, so as to create a potential 'template' for integration into Standard Operating Procedures (SOPs). These accommodate established 'Good Laboratory Practice' (GLP) and also can meet the requirements for governance of the translational research framework.

4 Discussion:

The reality is that major scientific endeavour is now a global exercise. It is the ability to rapidly configure groups to focus on challenges and complete stages effectively that will ensure their long term survival. Virtual Research Environments (VREs) are likely to play a central role in this in the future.

This means that the teams need to respect the logical transition and the consistent extrapolation of an argument from one step to the next. It is the provenance of data which ultimately secures the foundation of clinical intervention in a sound basic science evidence base. We must all adapt our technologies to ensure rapid, reliable and robust transfer through the progressive levels of readiness to the point that they can be implemented safely and securely for the benefit of all. The integration of the automated EMG signal processing in the Rehabilitation Robotics Sandbox reflects this philosophy.

5 Conclusions:

At different stages of the translational research pipe, demonstration of the consistency of EMG patterning across the validation steps, coordinated with consistent kinematic data collection, suggests that the wheel could transition to its next step for development, with confidence that it effectively adds value, passing through 'soft' and 'hard' governance review processes. These 'gates' included design reviews, ethical committee reviews and both preclinical and clinical trials.

This demonstration supported real collaboration across multidisciplinary teams representing Neurophysiology, Engineering, Rehabilitation Medicine and Orthopaedics. It covered initial University research and development (TRL1-3) plus engineering and evaluation in a healthy population, (TRL4-6) development stages. Rapid transition through to a nationally supported (UK NIHR i4i FDP1) clinical trial of spinal cord injured patients (TRL7), demonstrates the potential for this approach to develop a truly competitive edge in a global research and development environment.

6 Acknowledgements:

This multidisciplinary work is set in the context of established teams collaborating across Alberta

The philosophy is widely established across other centres in the musculoskeletal domain, representing the foundations of the evolving 'Campus Alberta'

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