

Victorian Comprehensive Cancer Centre

Identifying our Opportunities in Translational Research

A Clinical Oncological Society of Australia and Victorian Comprehensive Cancer Centre workshop

12 November 2010

WORKSHOP SUMMARY

Workshop report prepared for COSA by ZEST Health Strategies

INTRODUCTION

Laboratory and clinical research both have key roles to play in improving outcomes for people diagnosed with cancer. Outcomes from such research not only contribute to the development of new approaches to prevention, diagnosis and treatment but also inform best practice clinical practice guidelines designed to improve and standardise patient care across the cancer journey. These outcomes provide a rigorous evidence base for improving cancer control in Australia and worldwide. In an increasingly competitive market, the ongoing benefits of such research activity will only be realised to the fullest extent through consolidation of effort and expertise.

Effective, mutually beneficial links between laboratory and clinical settings allow new targets and treatments that are discovered and tested in the laboratory to undergo testing in appropriately designed, randomised, multicentre clinical trials. Collaboration is essential to ensure that patient numbers are sufficient to generate meaningful results. This is becoming increasingly important, given that, as technologies become more sophisticated and treatment becomes better targeted to individual needs, the population available to test specific research questions is significantly reduced in size. The link from clinic to laboratory is equally important, with investigation at a laboratory level of blood, tumour or tissue samples collected through clinical settings essential to assess the benefits, risks or lack of impact of a given intervention on particular sub-populations of patients.

Recognising the importance of collaboration between these two important areas of research, the Clinical Oncological Society of Australia (COSA) and Victorian Comprehensive Cancer Centre (Victorian CCC) hosted a workshop in November 2010 involving stakeholders involved in clinical and laboratory-based research. The aim of the workshop was to identify opportunities and approaches for mutually beneficial collaboration between laboratory and clinical cancer research communities with a view to enhancing translational research activity in Australia.

About the workshop hosts

The Clinical Oncological Society of Australia (COSA) is the peak clinical body representing all providers of cancer care. The overarching mission of COSA is to develop and maintain high-quality clinical care for cancer patients in Australia. The COSA membership is involved in 22 cancer professional groups, 6 cross-disciplinary interest groups and the 14 national CCTGs.

The Victorian CCC is under construction in Melbourne and is due for completion in 2015. It will be used by clinical and research staff from the Peter MacCallum Cancer Centre, Melbourne Health (which includes The Royal Melbourne Hospital), The University of Melbourne, Ludwig Institute for Cancer Research Melbourne – Parkville Branch, Walter and Eliza Hall Institute of Medical Research, The Royal Women's Hospital and The Royal Children's Hospital. The seven members have established the Victorian CCC as a joint venture.

WORKSHOP OVERVIEW

COSA and the Victorian CCC held a workshop on Friday 12 November 2010 at the Melbourne Exhibition and Convention Centre, following the 37th COSA ASM. The workshop program was developed by a multidisciplinary working party (see Appendix I) and was attended by stakeholders involved in clinical research, basic science and anatomical pathology (see Appendix II). The workshop was facilitated by Professor David Goldstein.

The workshop opened with presentations from national and international experts, providing a comprehensive overview of the status of translational research in Australia and internationally. Presenters described some of the issues facing clinical and basic scientists and gave some working examples of how translational research has led to improvements in the availability of clinical cancer treatments in Australia and overseas. The presentations were:

- Biology as the foundation of the clinical trial: time to return to basics Professor Andrew Biankin, Head, Pancreatic Cancer Research Program, Garvan Institute of Medical Research
- Pathology: a core support for translational research Professor Paul Waring, Professor of Pathology, University of Melbourne
- The evolution of the CCTG: what do the next 5 years hold? An ANZBCTG
 perspective
 Professor John Forbes, Director of Research, ANZBCTG
- Practical approaches to managing the legal and ethical issues Dr Nik Zeps, Research Manager, St John of God Pathology
- **Predictive versus prognostic biomarkers: the statistician's perspective** Dr Chee Lee, Research Fellow, NHMRC Clinical Trials Centre
- This Great Southern Land: ensuring inclusion of all Australians in clinical trials Dr Craig Underhill, Medical Oncologist, Border Medical Oncology
- Australia's global role in clinical trials: it's time to look beyond our shores more than ever

Professor Steve Ackland, Chief Investigator, COSA and CCTGs Enabling Project

- EMPathy Breast Cancer Network Professor Erik Thompson, Associate Professor and Principal Research Fellow, Director of Research, O'Brien Institute
- Can we learn from evolutionary biology as to how we can organise to cure cancer?

Professor Edison Liu, Executive Director, Genome Institute of Singapore (GIS)

The background presentations were followed by facilitated group discussion and plenary feedback. Participants were encouraged to consider local and international drivers for increased collaboration between clinical and laboratory-based scientists as well as barriers to the conduct of translational research. In doing so, participants were asked to identify priority needs in terms of infrastructure, resources and governance that would contribute to an efficient and sustainable Australian system for translational research.

This report provides an overview of key principles and themes identified in the background presentations, as well as a summary of the main issues, recommendations and goals that emerged from the group discussion.

WORKSHOP OUTCOMES

The workshop highlighted the significant role played by both clinical and laboratory research in driving improved outcomes for cancer patients in Australia and worldwide. The foundation of the workshop was that translational research – from laboratory to clinic and from clinic to laboratory – is essential to progress knowledge, identify and test new targets and explore the impact of treatments in specific sub-populations of patients. Opening the workshop, Professor Bruce Mann noted that Australia's competitive edge in this arena can only be maintained through consolidation of effort and expertise. He highlighted the critical importance of collaboration between laboratory scientists, pathologists, clinicians, clinical researchers and sponsors to ensure that Australia is an active and productive contributor to the global cancer research agenda and can reap the benefits of this contribution.

Background presentations: key themes

The background presentations provided a comprehensive overview of the purpose and status of translational and clinical research in Australia, and highlighted examples of how translational research activity has led to the development of innovative and targeted cancer therapies to date. Presenters reflected on challenges and priorities in the conduct of both translational and clinical research – both at a national and international level. Key themes arising from the presentations are summarised below.

Central to a number of presentations was the importance of generating reliable, interpretable and relevant data, supported by robust scientific design, appropriate analysis and careful interpretation of results. The value of cross-discipline collaboration to achieve such data was also emphasised.

Targeted therapies and the translational research agenda

One reason why translational research is essential is that cancer is a heterogenous disease that does not respond uniformly to treatment. A greater understanding of the molecular taxonomy of tumours provides the opportunity to stratify and better select patients for clinical trial participation, to stratify trial participants for subgroup analysis, and ultimately to identify patients who will benefit from targeted treatment. Such stratification results in smaller subgroups of patients likely to benefit from individual treatments, reducing the pool of patients available to participate in individual research studies. An outcome of translational research activity is individualised or personalised treatments that target the specific molecular characteristics of a tumour, resulting in improved treatment efficacy and ultimately better patient outcomes. On a broader scale, translational research provides the opportunity to translate the results of clinical and scientific research into changes in policy and clinical practice to optimise prevention, diagnosis and treatment.

Translational research includes the analysis of biospecimens to generate a panel of biomarkers. Biomarkers may be prognostic (factors that classify an individual's baseline risk of having a clinical event) or predictive (factors that classify an individual's response to treatment). Thus, identification of biomarkers has the potential not only to develop treatments tailored to tumour geno-/phenotype but also to provide predictive information to assist in identification of pathways to drug resistance and recurrence.

Much of the discussion during the workshop focused the on the process of identifying biomarkers that identify therapeutic targets. Professor Paul Waring noted that around one in five targets identified in pharmaceutical company drug pipelines proves to have success as a therapeutic target in clinical trials. It was emphasised that organisation of biomarker panels is necessary to ensure that testing is only undertaken for those targets for which an actionable outcome exists and that clinically relevant biomarkers must be supported by appropriate decision-making tools.

Types of biomarker trials

Dr Chee Lee described a range of trial designs used in the identification of targeted therapies:

- an **unselected design**, in which patients are tested and stratified according to biomarker expression, with both groups subsequently randomised for treatment; this design is useful if the biological evidence to limit treatment to biomarker positive patients is unclear
- a **hybrid design**, in which patients are stratified and treated according to both biomarker expression and clinicopathologic characteristics
- a **retrospective analysis** of biomarker expression in tissue samples collected during a clinical trial with a test of interaction undertaken to identify any relationship between response and biomarker expression
- an **adaptive design**, in which the utility of multiple new treatments is explored within several strata of biomarkers, with efficacy information used to influence randomisation; this design is useful for screening trials to identify promising agents for phase III testing.

Describing the differences between prognostic and predictive biomarkers, Dr Lee highlighted the importance of validating biomarker expression as a surrogate endpoint for treatment response. He commented that a strongly prognostic factor may not necessarily be a good surrogate biomarker for assessing treatment effect, with a true surrogate needing to convey both prognostic and predictive abilities. He gave examples of how the same biomarker can be predictive in one tumour type but not in another and how retrospective analyses may not be sufficient to establish the utility of a biomarker.

Key steps in developing genomic-based treatments

A number of the presentations included issues to be considered when developing therapies targeted to expression of a particular biomarker:

- the success of phase III trials of targeted therapies rely on selecting the correct patients for the trial; the sample size required to demonstrate efficacy differs according to biomarker prevalence
- an enrichment strategy is an important step in trials of targeted therapies to ensure that patients who are unlikely to benefit from the treatment are excluded appropriately from those clinical trials
- appropriate patient selection (and in turn exclusion) in clinical trials of targeted therapies requires the use of the correct assay to ensure that the biomarker of interest can be reliably identified; one speaker commented that the assay is becoming as important in defining a clinical trial as the underlying clinical trial question
- the choice of the correct assay relies on there being a measurable detection threshold for the biomarker of interest and on the assay providing reliable results that do not vary over time
- for clinical trials of targeted therapies, a validated diagnostic test must be in place prior to recruitment of the first patient into the phase III trial
- whether it is more appropriate for biomarker assays to be undertaken centrally by units with a high throughput and level of expertise or whether (with standardisation and accreditation) testing can be undertaken locally by all pathology laboratories
- where a clinical trial is exploring the response to a targeted therapy based on biomarker expression retrospectively, the trial must be adequately powered to identify a responder subset if there is no response in the overall population
- translation of results from a trial-based setting to community-based testing can be complicated if measurement of a particular biomarker is not standardised.

Presenters highlighted the importance in translational research of functional partnerships between laboratory scientists, pathologists, diagnostic companies, drug development companies and clinical researchers. The importance of quality assurance mechanisms was also flagged as a key step in ensuring that assays are undertaken appropriately, thereby avoiding the risk that patients will miss out on effective treatments because of poor laboratory testing.

Issues with tissue collection in translational research

Collection and storage of tissue samples is an important step in translational research. Professor John Forbes identified three orders of tissue collection:

- global collection of tissue in the context of an international, multicentre trial
- national collection of tissue in the context of a cancer cooperative trials group study
- collection of tissue by an institution for the purposes of research and treatment planning.

While it was acknowledged that the issues and requirements underpinning each level of tissue collection are likely to vary, a number of common issues surrounding the collection and use of tissue samples for translational research activity were identified:

- biomarker research and testing is dependent on there being sufficient tissue available to undertake a particular assay; for some cancers, such as bronchoscopic biopsies for lung cancer, available samples are small and used almost entirely for diagnostic purposes
- collection, processing and storage of tissue samples for biomarker analysis, and subsequent retrieval of samples, requires considerable effort and expertise
- sites undertaking translational research activity should have adequate resources to undertake tissue collection and storage
- the costs of sample collection, storage and retrieval are not commonly factored into costing models.

The translational research agenda in Australia

Dr Craig Underhill and Professor Steve Ackland provided an overview of the national status of clinical research. In doing so, they also reflected on some broader issues around the conduct of cancer cooperative clinical trials and translational research in Australia, including the need to:

- ensure equity of access to clinical trials for people from regional communities and for people from population and community groups who are commonly under-represented in clinical trials
- increase the number of cancers for which clinical trials and translational research are undertaken
- increase patient accrual to clinical trials
- raise the priority given to the conduct of clinical and translational research in hospitals
- maintain Australia's position internationally as a location for high-quality clinical and translational research
- identify where Australia's research effort can best be invested for example:
 - $\circ~$ as participants in international multicentre research studies
 - \circ in the conduct of boutique research studies in niche areas
 - $\circ\;$ in the conduct of research with value-add components such as quality of life issues and pharmacogenomics
- improve the cost-effectiveness and efficiency of clinical research activity to maximise use of limited resources.

In discussing future opportunities for clinical and translational research in Australia, a number of presenters reflected on a number of barriers, particularly in the approval and start-up phase. Identified barriers included the level of regulation for clinical trials as well as complexities of ethical approval for clinical and translational research activity. While the introduction of the Harmonisation of Multicentre Ethical Review (HoMER) initiative aims to avoid duplication in ethical review, its use is not currently mandated and uptake relies on individual institutions adopting strategies to accept ethical review from another committee. A further problem highlighted related to the fact that clinical trials are seen by some hospital administrations as a financial burden and trials may be required to include payment for what would be routine care outside the clinical trial setting.

Ethical issues in translational research

Dr Nik Zeps discussed the importance of ethical approval as one component of regulatory compliance and governance, highlighting the need for researchers and ethics committees to understand and appropriately apply ethical principles to research design and conduct. In doing so, he provided a summary of the key principles underpinning the *National Statement on Ethical Conduct in Human Research* (2007):¹

- 1. **Research integrity and merit**: research should focus on important questions and should be undertaken by appropriately trained and experienced individuals
- 2. **Justice**: the scope, objectives and approach to the conduct of research must be fair, with no exploitation of participants, and fair access to the benefits of the research
- 3. **Benefience:** likely benefit of the research must justify any risks of harm or discomfort to participants
- 4. **Respect**: consideration of issues such as privacy, cultural sensitivities, and the capacity of individuals to make their own decisions

Dr Zeps highlighted a number of questions related to ethical review of translational research:

- **unspecified consent**: whether it is appropriate for samples collected during an investigation or study in one disease type to be made available for research in another disease area
- **feedback**: whether the results of biomarker analysis should automatically be provided to the individual
- **cross-border access to tissues**: how the results of biomarker testing for samples stored overseas as part of multicentre research studies can be accessed.

Managing patient consent for biospecimen collection and subsequent access to samples was the topic of discussion during several of the presentations. Anecdotal reports were shared suggesting that patients are generally supportive of the use of biospecimens for research and that some may agree to multiple biopsies during the cancer journey if required. Several presenters reflected on whether lessons can be learned from the private sector in terms of speed of approval, start-up and ethical approval for research activity.

Questions for consideration

Throughout the presentations, a number of questions were raised in relation to translational research and biomarker testing, including:

- how to fund drugs for clinical trials that are not attractive to the pharmaceutical industry
- whether the cost of development justifies the expense of treatments targeting rare biomarkers

¹ National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee. National Statement on Ethical Conduct in Human Research. Canberra: Commonwealth of Australia, 2007. COSA and Victorian CCC Translational Research Workshop Summary

- who 'owns' biological specimens collected during clinical trials and how widespread access for research purposes can be facilitated
- who should fund the costs of tissue collection and storage for translational research.

Examples of collaborative translational and clinical research activity

Throughout the presentations, a number of examples of collaborative translational and clinical research initiatives were described.

- Australian Pancreatic Cancer Genome Initiative a collaboration of sites in Brisbane, Sydney, Adelaide, Melbourne and Perth who are participating in the IMPACT trial, which aims to generate individualised treatments for pancreatic cancer based on sequencing.
- PRIME a consortium of 16 investigators in NSW, established by Cancer Council NSW and Cancer Voices Australia to drive a coordinated and integrated effort in personalised medicine for cancer through collaboration, best use of resources, training and advocacy.
- EMPathy Breast Cancer Network a national network of researchers working together with funding from the National Breast Cancer Foundation to eradicate breast cancer recurrence through the investigation of the role of epithelial mesenchymal plasticity (EMP) in breast cancer metastasis. Guided by a Scientific Advisory Committee, the network aims to validate novel methodologies, develop new breast cancer diagnostics and identify new biological targets.
- Cancer Cooperative Trials Groups Enabling Project an NHMRC-funded initiative aiming to increase collaboration and ensure effective use of resources by Australia's 13 cancer cooperative trials groups.

International perspective

Professor Edison Liu provided a fascinating insight into the approach used to guide research activities in the Genome Institute of Singapore (GIS). In doing so, he applied lessons from evolution to the description of optimal models to encourage clinical and translational cancer research. Key principles underpinning the GIS research strategy are the importance of adaptability and diversity of approach, with incremental benefits in knowledge achieved by testing a diverse range of theories and allowing for random errors to be made.

The GIS integrates technology with biology and medicine with the aim of addressing important questions ranging from fundamental science through to population studies. In describing the GIS model, Professor Liu described the value of identifying and adapting to a conceptual niche rather than taking an 'engineering' approach of identifying and testing solutions to a specific problem. The research team comprises a team of around 260 scientists with expertise in genomics, cell biology, medicine and population genetics. Professor Liu described the 'Darwinian Success' of the GIS model, explaining that research is guided by the best scientific questions, research success is rewarded with increased resourcing and the lower 10% of the research pool is routinely removed. He described the optimal organisational structure for research as one that relies on collective reasoning by a group of individuals with diverse skill sets, while acknowledging the need for an 'alpha dog' to make decisions about direction where necessary. Flexibility and adaptability were flagged as essential components of the model, supporting innovative thinking and rapid consideration of priority issues where required.

Professor Liu described the approach to GIS research projects as involving 'swarming' and 'convergence', with the research team competing as a collective of individual experts to reach the required goal. He likened the research effort to that of a rugby game, in which the ball is passed from one team member to another, with the primary aim not based on who carries the ball but on the end result of scoring a try.

Recommending approaches to improve cancer outcomes in a cost-effective manner using the best science possible, Professor Liu identified the following steps:

- · identify key questions whose solution would be critical
- identify quantitative endpoints for a research strategy that are achievable:
 - o X% into clinical trials nationally
 - o Y% reduction in mortality in 3 diseases
 - o Z% reduction in costs for care in three diseases
- examine metrics frequently and transparently
- focus resources appropriately rather than distributing them democratically.

Outcomes from group discussions

Workshop participants participated in one of two facilitated small group discussions, focused on identifying priorities for enhancing Australia's capacity for translational research activity. Both groups identified that the conduct of translational research depends on the availability of biospecimens collected from clinical trials. A starting point for discussion was therefore how to **enhance clinical trial activity in Australia**. Identified priorities included the need to:

- identify the **strengths** of Australian clinical trials (eg value add components such as quality of life and health economics) and areas for improvement
- identify the **optimal focus** of Australia's clinical research effort (eg industry vs investigator initiated trials; large multicentre vs boutique trials)
- design clinical trials that are relevant to Australia's health system
- increase the **size and capacity** of Australia's clinical research workforce, through networking, collaboration, education and mentoring
- increase the efficiency of clinical research activities through standardisation of processes, communication and by removing unnecessary formulaic obstructions
- advocate for increased funding for clinical research (focusing on government and funding bodies)
- advocate for research to be embedded as **core business** for health services and hospitals (focusing on hospital and health service CEOs), requiring:
 - o defined KPIs
 - o protected time for health professionals to participate in research activities
 - o hospital funding for the care of patients in the control arm of investigator-driven trials.

These priorities highlighted the need for meaningful data about clinical research activity that can be used for benchmarking and to measure progress. The importance of identifying what data and information are required to influence policy makers and funders, and how best to communicate this information to these decision makers, was also emphasised.

Participants also discussed specific **barriers**, **enablers and infrastructure requirements for translational research** in Australia. Feedback has been consolidated into a number of theme areas and is summarised in Table 1 (overleaf).

Goals for the future

The group discussions generated a number of aspirations or goals to drive progress in clinical and translational research in Australia. These included aiming to:

 engage anatomical pathologists and their staff in the broad agenda of enhanced biobanking for clinical trials

- optimise and harmonise data collection systems used for biobanks and clinical trials
- · increase the number of clinicians participating in clinical cancer research
- increase the number of cancer clinical trials designed specifically for the Australian context
- increase opportunities for dialogue between laboratory and clinical researchers
- increase the number of cancer clinical trials that incorporate biological questions
- adhere to minimum global standards for the collection storage and handling of biospecimens
- increase Australia's representation on international committees that approve biological sub-studies for cancer clinical trials
- routinely evaluate and report successes and progress in cancer clinical and translational research.

The need for a business case that clearly articulates the importance of clinical and translational cancer research for the Australian population was seen as a priority for supporting progress in this important area.

Next steps

Professor Bruce Mann closed the workshop by thanking participants for their input, acknowledging the role of the Working Party, COSA and the Victorian CCC in planning and organising the workshop.

COSA will use the outcomes from the workshop to develop a business case designed to address the issues and priorities identified by workshop participants. The business case will be discussed at a second workshop in 2011.

COSA, the Victorian CCC and other key stakeholders should continue to look for opportunities for collaboration to continue to progress work in this important area.

Theme	Key issues	Recommendations
Role of pathology	 Anatomical pathology is central to the success of translational biology 	 Pathologists should be engaged and involved in clinical research projects that have a translational component from the outset
	 Pathology laboratories are at risk of being viewed as a 'public library' with an expectation that samples should be made available on request 	 Biospecimen processing and acquisition should be supported as 'core business' and funded accordingly
		 Guidelines should be developed outlining appropriate pathways for requesting access to samples
	 Pathology laboratories are not currently adequately funded to process and retrieve samples for translational research 	 Research protocols and review processes should recognise the involvement of all relevant individuals, including pathologists and laboratory scientists, and should clearly identify likely requirements for
	 Requests to process biospecimens for storage during clinical trials can be included as an 'add on' rather than a clear requirement from the outset 	biospecimen collection and access from the outset
Role of laboratory scientists	 Generation of translational research strategies requires functional collaboration between laboratory-based and clinical researchers 	 Opportunities should be sought to facilitate communication and interaction between laboratory and clinical research COSA and the COTCe should each appartunities to run integrated fore
	 Efforts to provide fora for communication between laboratory and clinical researchers to date have had limited success 	 COSA and the CCTGs should seek opportunities to run integrated for involving laboratory scientists and anatomical pathologists
Infrastructure requirements	An integrated model for translational and clinical research requires data systems that cut across both systems	 Opportunities should be sought for integrated approaches to translational research that comprise both clinical and translational expertise
	 Biobanking requires appropriate equipment for tissue collection and storage 	 A business case should be developed articulating the minimum infrastructure requirements to support high-quality translational research activity, and the expected outcomes of such investment
		 Platform-based funding models should be considered that address economies of scale and justify investment in non-industry funded research

Table 1: Issues and recommendations for enhancing translational cancer research in Australia

Theme	Key issues	Recommendations
Regulatory barriers	 Time to approval of trials is longer in Australia compared with other countries 	 Further opportunities should be sought to standardise procedures and encourage shared approaches that will expedite trial approvals
	• Standardisation of approaches, including clinical trial agreements, umbrella insurance policies and harmonisation of ethics is assisting in reducing approval times for clinical trials	 Potential barriers to ethical approval relating to consent, including waiver of consent for access to samples and feedback about the results of biospecimen analysis, should be further explored
		 Ethics committees should be educated about specific issues relating to translational research
Quality assurance	 The availability of high quality samples for future research requires skills in tissue preparation and retrieval Comparability across samples is dependent on standard approaches to sample preparation and fixing 	 Shared standard operating procedures should be developed and implemented across biobank sites
		Large-scale central repositories should be considered for biospecimen
		storage, particularly for tissue samples (less important for blood samples which can often be collected and stored locally)
Advocacy	Advocacy is an important enabler to drive capacity and funding for clinical research that includes a translational component	 A greater understanding of the priorities and drivers for policy makers and funders should be sought
		 Consumers should be engaged as active partners in advocating for clinical and translational research funding and infrastructure

APPENDIX I: WORKING PARTY MEMBERSHIP

Name	Organisation
Steve Ackland	Chair COSA & CCTG Enabling Project
	Newcastle Mater Misericordiae Hospital
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	Royal Melbourne Hospital
Clara Gaff	Victorian Comprehensive Cancer Centre
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Bruce Mann	President, COSA
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Nik Zeps	St John of God Pathology

APPENDIX I: WORKSHOP PARTICIPANTS

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Name	Organisation
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