



DATA SHARING AND RELEASE LEGISLATIVE REFORMS

A SUBMISSION IN RESPONSE TO
THE DISCUSSION PAPER

October 2019

ABOUT RESEARCH AUSTRALIA

Research Australia is the national alliance representing the entire health and medical research pipeline, from the laboratory to patient and the marketplace.

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our role:

Engage
Australia in a conversation
about the health benefits
and economic value of its
investment in health and
medical research.

Connect
researchers, funders
and consumers to
increase investment
in health and medical
research from all sources.

Influence
government policies that
support effective health
and medical research
and its routine translation
into evidence-based
practices and better
health outcomes.

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Summary of recommendations

Research and Development and a Public Benefit Test	<p>The Data Sharing and Release legislation should include a definition of Research and Development identical or similar to that used by the ABS.</p> <p>The question of what type of research and development should be eligible for Data Sharing should be addressed with a separate Public Benefit test.</p> <p>The Public Benefit test needs to address issues including the directness, certainty and immediacy of the benefit.</p> <p>The Public Benefit test should be applied after a determination has been made that the proposal for data sharing is to inform or enable research and development.</p>
Commercial Use	<p>If there is a public benefit, the question of commercial interest should be irrelevant, and a separate commercial use test should not be required. This recognises that we live in a market-based economy, where many goods and services are provided by the private sector.</p> <p>But if commercial use is to be considered separately, then a test will need to be applied. Factors to be considered as part of this test could be:</p> <ul style="list-style-type: none"> • The relative scale of the public and private benefit, i.e. a proposal might fail the test if the private benefit is disproportionately greater than the public benefit. • How certain is the commercial use- i.e. is it immediate, or is commercialisation a future possibility? • Is the creation of jobs and the taxation of income a public benefit that should be considered? <p>If a commercial use test is to be applied, some simple rules could streamline the process. For example, an application by a university, medical research institute or publicly funded research organisation could be exempted from the commercial use test. This recognises that research undertaken by these organisations may eventually lead to commercial products and services, and that there is explicit support in Government for these outcomes.</p>

Commercial Use	Research and Development for a medicine, medical device or therapeutic could be exempted from the test on the basis that there is a clear and overriding public benefit in the preservation and improved quality of human life.
Implementation of tests	Incorporating detailed tests for public benefit and commercial use into the legislation would be difficult. It would be more appropriate to provide the framework for the Public Benefit test and any Commercial Use test (if the latter is considered necessary) and their application in the legislation, with the detail to be provided in guidance published by the National Data Commissioner.
Privacy Act 1988	The vast majority of universities in Australia are created by and/or governed by specific legislation enacted by state governments and are not covered by the Privacy Act 1988. Consideration should be given to whether universities and other organisations not subject to the Privacy Act 1988 can be required by contract or other binding agreement to comply with specific terms and conditions that will apply equivalent privacy coverage on relevant matters.
Ethics Approval	<p>Research Australia submits that there should not be an expectation from Data Custodians that all 'safe' Data Sharing proposals from researchers require the approval of a Human Research Ethics Committee.</p> <p>There should also be no expectation that a Data Custodian should require a Data Sharing proposal to obtain approval from a Human Research Ethics Committee as part of the Data Custodian's own vetting and assessment of a Data Sharing application.</p> <p>The assessment of ethical considerations by the Data Custodian and the role of the National Statement for Research Ethics should be addressed in guidance by the National Data Commissioner.</p>

DATA SHARING AND RELEASE LEGISLATIVE REFORMS

Introduction

Research Australia welcomes the opportunity to make a submission to the Department of the Prime Minister and Cabinet in response to the Discussion Paper.

Research Australia is the peak body for Australia's health and medical research and innovation sectors. Our members strive to create new knowledge and develop new medicines, therapies, technologies and interventions that can deliver better health outcomes and improve human health and wellbeing.

Data is critical to this work, including data about our health, the medications we use, and the health services we utilise. The use of this data for research purposes is supported by most Australians. Research Australia has undertaken annual opinion polling since 2003. Our polling captures the public's views on a range of matters relating to their health, healthcare delivery, and the role of research.

We regularly poll Australians about their attitudes to the use of personal health data for research, and the response is always positive. In our 2017 poll we asked people about the use of patient's medical records by health and medical researchers. There was overwhelming support, with 48% strongly supportive and 45% somewhat supportive. Only 7% of Australians were not supportive of doing so.¹

Research Australia is strongly in favour of the proposed legislation and we support the direction outlined in the discussion paper. In this submission we have chosen to address specific issues relating to data sharing for the purposes of research and development. These include:

- the purpose test;
- public benefit and commercial use;
- Privacy Act coverage; and
- the role of ethics approval.

¹ Research Australia, Australia Speaks! Research Australia Opinion Polling 2017 p.9

Purposes, Public Benefit and Commercial Use

The Discussion paper proposes that the legislation allow data sharing for three purposes:

- Research and Development
- Policy and Programs
- Service Delivery

Research Australia is supportive of these three purposes, and notes that they are not necessarily mutually exclusive. For example, researchers from a research organisation can partner with a government department in research that advances knowledge and creates better public policy (Research and Development) and the same project can have the objective of helping plan for the future and make decisions about what health services to fund (Policy and Programs). Researchers can also partner with government departments to improve service delivery.

The sharing of data for one of the above purposes must also be for public benefit. The Discussion Paper indicates consideration is still being given to how to 'preclude commercial uses not delivering public benefits' (p.57)

Research Australia believes the interaction between the purpose, public benefit, and commercial uses must be carefully considered in drafting the legislation, and we further explore these interactions in this part of our submission.

Defining the purposes

How the three purposes are defined will be critical to the success of Data Sharing.

Of particular interest to Research Australia is the Discussion paper's definition of **Research and Development** (R&D) as '*activities to advance knowledge, contribute to society and create better public policy, undertaken by a range of actors including universities and the private sector.*' (page 56).

Advancing (or increasing) knowledge is a common element in a definition of research (see below) but 'contribute to society' and 'create better public policy' are more problematic. There are many activities that contribute to society which would not be considered R&D. For example, donating money to a charity or volunteering at a shelter for homeless people would generally be considered to contribute to society but these activities are neither research nor development.

The definition of R&D used in the Discussion Paper attempts to embed the public benefit test in the definition of research and development when these two concepts should be considered separately.

The other two purposes are not defined in the Discussion Paper, suggesting that informing and enabling 'government policy and programs' and 'government service delivery' are considered to be more self-explanatory. It also suggests that these two purposes are intrinsically for the public benefit in a way that R&D is not.

Together and individually, Research and Development are important concepts that have established meanings in several different contexts. The Australian Bureau of Statistics regularly collects and reports data on Research and Development.

'R&D, as collected by the ABS, is defined in accordance with the Organisation for Economic Co-operation and Development (OECD) standard as "creative and systematic work undertaken in order to increase the stock of knowledge - including knowledge of humankind, culture and society - and to devise new applications of available knowledge".'²

For further interpretation of the definition of R&D, the ABS references the *Australian and New Zealand Standard Research Classification (ANZSRC)*, 2008 (currently under review) and the OECD publication *The Measurement of Scientific and Technological Activities: Proposed Standard Practice for Surveys of Research and Experimental Development - Frascati Manual 2015*.³

The Australian Government provides tax incentives for certain Research and Development activities. To distinguish between R&D activities that are eligible for the Research and Development Tax Incentive (RDTI) and those that aren't, the Income Taxation Act 1997 defines 'core R&D activities' and activities that are considered not to be core R&D activities.⁴ A similar approach could be adopted for the Data Sharing Legislation, identifying R&D activities eligible for data sharing and those that are not, although Research Australia believes this approach is problematic. The RDTI definition is provided as Appendix 1.

The definition of core activities is relatively short. The list of activities that are not core activities is significantly longer, reflecting experience with claims for the tax incentive over many years. It is a list of activities that might normally be considered to be research and development but which are not eligible for the R&D Tax Incentive, and reflect public policy considerations about what is to be supported by the tax incentives. The list of non core activities is accompanied by guidance and rulings from the ATO.

Research Australia is **not** proposing that the Data Sharing legislation take this approach to listing R&D activities which are not eligible for Data Sharing; the long list of non core activities and the need to regularly issue new guidance are illustrative of the disadvantages of this approach.

If the Data Sharing and Release legislation creates a new definition of Research and Development, it is important that it is appropriately framed, and that it is developed with careful consideration for how it will interact with the other purposes and the public benefit test.

Research Australia submits that the Data Sharing and Release legislation should include a definition of Research and Development identical or similar to that used by the ABS. The question of what type of R&D should be eligible for Data Sharing should be addressed with a separate Public Benefit test.

This approach involves a two (or potentially three) stage sequential assessment process:

- (1) Is the data sharing request for an approved purpose?**
- (2) Is there a public benefit from sharing the data?**
- (3) Is there a commercial use (private benefit)?**

² <https://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/8104.0Explanatory%20Notes12017-18?OpenDocument>

³ <http://www.oecd.org/sti/inno/frascati-manual.htm>

⁴ Income Tax Assessment Act 1997 - Section 355.25

A Public Benefit test

While the Discussion Paper alludes to the need for there to be a public benefit for any data sharing to occur under the Data Sharing Legislation, there is no discussion about how the public benefit should be identified or measured, and what would be a sufficient public benefit for data sharing to be permissible.

Factors to be considered here are:

- How direct does the public benefit have to be?
- How certain does the public benefit have to be?
- How immediate does the public benefit have to be?

How direct does the public benefit have to be?

There are a number of factors that need to be considered in relation to how direct or indirect the public benefit can be.

- Is the advancement of knowledge a sufficient public benefit? The research being undertaken may be basic or exploratory research without a clear future application.
- Is using the data for research and development that generates revenue, creates jobs and leads to paying tax a direct enough public benefit?
- What if the research will largely benefit an overseas population? (For example, comparative research conducted in Australia and several other countries by an international collaboration leads to the adoption of Australian models of education, healthcare provision etc. in other countries.)
- What if the research is of benefit to only a small proportion of the community?
- Does there have to be a public benefit for the specific subpopulation whose data will be shared? (For example, research into a cohort of aged people may lead to future aged care reforms, but beyond their own lifetime.)

How certain does the public benefit have to be?

Research is by its nature experimental. While a researcher may have expectations about what the outcomes for the research will be and how the research could be utilised, the hypothesis may not be supported by the evidence and the research might lead to a 'dead end'.

Even if successful, the research proposal may only currently be funded to complete the research and publish the findings. Public benefit could come from the research being used and further developed but this is beyond the current project, and the prospect of funding for further development and translation of the research may be unknown.

Is the potential for future public benefit sufficient or does there need to be a degree of certainty that the public benefit will be achieved? If so, what is the level of certainty required and how will it be assessed?

How immediate does the public benefit have to be?

Research and development can have long timelines. The realisation of public benefit may be dependent on factors beyond the research, such as the adoption of the findings by a policy making body. Or the public benefit may only be realised if the research findings are publicised and acted on by the public, such as reducing salt intake. This public benefit may not be evident for

years, or even decades. Is there an expectation about the timeframe within which the public benefit must occur?

Research Australia submits that the Public Benefit test needs to address the issues raised above.

Research Australia submits that the Public Benefit test should be applied after a determination has been made that the proposal for data sharing is to inform or enable research and development.

Application of a Public Benefit Test beyond R&D

As noted earlier, there appears to be a presumption that data sharing to inform or enable government policy and programs, or for government service delivery, is intrinsically for a public purpose. If this is the case (and Research Australia does not have a view on this), it may only be necessary to apply a Public Interest test to R&D data sharing proposals. If there is a view that a Public Benefit test is also required for either or both of these purposes, there may be other factors to be considered than those raised above.

Commercial Use

Research Australia notes the statement in the Discussion Paper that *'We are still considering how to preclude commercial uses not delivering public benefit'* (p.57). Research Australia submits that the application of a Public Benefit test distinct from the Purpose Test addresses this issue, at least in a narrow sense. If there is no public benefit then the commercial use will necessarily be precluded.

A more complex question is the extent to which commercial use should be weighed against the public benefit. Is the existence of any public benefit, however small, sufficient to justify data sharing which has a commercial use and may provide private benefits? Conversely, does any commercial use preclude data sharing, regardless of the public benefit that may accrue?

In relation to R&D, Research Australia submits that the answer to the former question is 'yes'; as long as there is a public benefit, the question of commercial interest is irrelevant and a separate commercial use test is not required. This recognises that we live in a market-based economy, where many goods and services of public benefit ('public goods') are provided by the private sector, or in partnership between the private and public sectors.

This is certainly the case in healthcare, where the private sector is heavily involved in the research, development and sale of health interventions such as medicines, therapeutics, and diagnostic and imaging devices and technologies. Even where research is initially publicly funded, the pathway to public benefit is often via the commercialisation of the research. This may occur, for example, through the sale or licensing of the intellectual property to an existing company or the creation of a new company.

The public benefit of these commercial products is evident in lives saved and improvements in quality of life. The value the broader community places on these products is evident in the very substantial public subsidies provided through the Pharmaceutical Benefits Scheme (Medicines), the Medicare Benefits Schedule (diagnostic tests and imaging), the National Immunisation Program (vaccines); and government funding of hospital, allied health and medical procedures. Better health

is a public good funded by the taxpayer and the consumer, delivered through the purchase of private sector goods and services as well as by the public sector.

However, Research Australia is also aware that, as reported in the Discussion paper, the commercial use of data is not supported by all sections of the community.

'We heard Australians are concerned about public sector data being used by the private sector. We are considering how to enable data sharing for research and development for commercial uses that benefit society, but do not harm individuals or businesses. Many stakeholders reflected that they were comfortable providing data to the government to receive better services and for government activities, but they did not want companies to access data to pursue their commercial interests. We are considering how to design the purpose test to maximise public benefits while meeting community expectations.

The purpose test cannot be considered in isolation. The Data Sharing and Release legislation presents holistic risk management, through the purpose test and the application of the Data Sharing Principles. We are not proposing preventing users' participation in data sharing based on their sector. Instead, the purpose test and the Data Sharing Principles are the avenues to prevent commercial uses not supported by the community. As yet we have not finalised our position on commercial use of public sector data. We welcome further discussions about this area to make sure we fully understand Australians' concerns. (P.27)

A Commercial Use test

If the conclusion of the Department is that the existence of any public benefit, however small, is not of itself sufficient to justify research and development with a commercial use, then a further test will need to be applied. We reiterate that this will only occur where an assessment has already been made that there is a public benefit.

Research Australia submits that factors to be considered as part of this test could be:

- **The relative scale of the public and private benefit, i.e. a proposal might fail the test if the private benefit is disproportionately greater than the public benefit.**
- **How certain is the commercial use- i.e. is it immediate, or is commercialisation a future possibility?**
- **Is the creation of jobs and the taxation of income a public benefit that should be considered?**

Research Australia submits that the application of any commercial use test would be complex, requiring significant time and resources, and the design of any such test would need to be considered carefully. The complexity and effort of applying such a test is a persuasive and pragmatic argument for not applying a commercial use test at all, and needs to be given serious consideration when deciding if commercial use is to be addressed in the legislation.

If a commercial use test is to be applied, Research Australia submits that some simple rules could streamline the process. For example, an application by a university, medical research institute or publicly funded research organisation could be exempted from the commercial use test. This recognises that research undertaken by these organisations may eventually

lead to commercial products and services, and that there is explicit support in Government for these outcomes.

Similarly, R&D for a medicine, medical device or therapeutic could be exempted from the test on the basis that there is a clear and overriding public benefit in the preservation and improved quality of human life.

Finally, Research Australia notes the capacity for commercial use of data sharing where the Data Sharing is undertaken for the other two purposes identified in the Discussion Paper. The Australian Government regularly partners with, or contracts services from, private sector organisations for government service delivery and to inform and enable government policy and programs. These arrangements need to be considered in the context of defining commercial use and assessing it in the context of Data Sharing applications.

Implementation of Public Benefit and Commercial Use tests

Research Australia submits that incorporating detailed tests for public benefit and commercial use into the legislation would be difficult. It would be more appropriate to provide the framework for the Public Benefit test and any Commercial Use test (if the latter is considered necessary) and their application in the legislation, with the detail to be provided in guidance published by the National Data Commissioner.

Consent

Research Australia acknowledges that there is also controversy in some quarters about the issue of consent. Research Australia is supportive of the position outlined in the Discussion Paper in Section 4.6 in relation to consent and endorses the position that requiring consent leads to biased research data, reduced utility for policy making and jeopardises the public benefit.

Research Australia supports the issue of guidance from the National Data Commissioner on when and how consent should be addressed.

Accreditation and Data Sharing

Research Australia is supportive of the two-tier framework proposed in the Discussion Paper for Accredited User Organisations and Accredited Individuals.

In relation to the training requirements for Accredited Individuals, using tools and resources provided by the National Data Commissioner would appear to be the most efficient and effective approach. This will provide a consistent national approach and streamline accreditation for individuals moving between Accredited Organisations. Accredited Organisations would still be required to accredit the individuals and ensure they meet site specific requirements.

Research Australia is also supportive of the proposed approach to Accredited Data Service Providers.

Privacy Act 1988

We note that the Discussion paper links accreditation to ‘demonstrating privacy coverage under the Commonwealth Privacy Act 1988 or equivalent’. (p.43)

The vast majority of universities in Australia are created by and/or governed by specific legislation enacted by state governments. As such, they are not covered by the Privacy Act 1988. The extent to which ‘equivalent’ provisions exist in State and Territory legislation will need to be assessed on a jurisdiction by jurisdiction basis.

Research Australia submits consideration should be given to whether universities and other organisations not subject to the Privacy Act 1988 can be required by contract or other binding agreement to comply with specific terms and conditions that will apply equivalent privacy coverage on relevant matters.

Ethical considerations

While not raised in the Discussion paper, there was discussion in the consultation attended by Research Australia about Ethics Approval of research, and how Data Custodians could place reliance on this in assessing the public benefit of a Data Sharing proposal.

Research Australia is concerned about creating an environment in which Ethics Approval for a research proposal might be automatically required by a Data Custodian as part of their own assessment criteria.

The Ethics Approval process is mandated by the *National Statement On Ethical Conduct In Human Research* (the Statement) and has been developed jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia.

The primary purpose of the Statement is to ensure that research subjects are protected from harm and treated with respect.⁵ It is a framework designed to cover a range of different types of research and risk, including experimental surgical procedures and new medicines where there is a risk of serious injury, disability and death.

The Statement recognises that many research proposals pose little or no risk to research subjects, in which case ethics approval may not be necessary. This research is described as low risk and negligible risk research.

Low risk and negligible risk research

The expression ‘low risk research’ describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

The expression ‘negligible risk research’ describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.⁶

Negligible risk research can be entirely exempted from the requirement for approval by a Human Research Ethics Committee by the researcher’s institution. (This assessment and decision is made by an approved person at the institution, not the researcher.) Low risk research can be given

⁵ National Statement on Ethical Conduct in Human Research 2007(Updated 2018). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra. P.6

⁶ Ibid, p.13

ethics approval through an alternative process that does not require approval by a Human Research Ethics Committee. (Once again, this assessment and decision is made by an approved person at the institution, not the researcher.)

Research using existing data sets with deidentified data is regularly determined to be negligible risk research. Research using existing datasets with identified data could be characterised as low risk research, depending on the nature of the data and the consequences for the individual if that data was to be made public.

Assessment by a Human Research Ethics Committee can be a time consuming, lengthy and resource intensive process, hence the alternatives provided by the Statement for negligible risk and low risk research. While we expect the vast majority of Data Sharing proposals by health and medical researchers to require approval by an HREC, there is likely to be a minority which would be negligible risk research projects under the Statement, and others which would be low risk.

Research Australia submits that there should not be an expectation from Data Custodians that all 'safe' Data Sharing proposals from researchers require the approval of a Human Research Ethics Committee.

There should also be no expectation that a Data Custodian should require a Data Sharing proposal to obtain approval from a Human Research Ethics Committee as part of the Data Custodian's own vetting and assessment of a Data Sharing application.

The assessment of ethical considerations by the Data Custodian and the role of the National Statement for Research Ethics should be addressed in guidance by the National Data Commissioner.

Research Australia notes that Data Sharing for the purposes of policy and program development and service delivery can also raise ethical considerations. It is not clear how, or if, these will be addressed by the legislation and guidelines.

Guidance to support best practice

Research Australia is supportive of the approach outlined in the Discussion Paper, by which the National Data Commissioner will issue non-binding guidance but also binding Guidance in the form of Data Codes. We note that the Commissioner 'will draw on existing resources and agencies such as the Australian Bureau of Statistics, the Office of the Australian Information Commissioner and the National Archives of Australia.' There is also significant expertise outside the Government in a range of areas including data management, data security and data linking. We encourage the National Data Commissioner to make use of these resources, and to consult with the research sector before guidance is published.

Conclusion

Research Australia envisions a world where Australia unlocks the potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Health and medical research enjoys strong public support because people recognise that health and medical research leads to safer, higher quality and more effective health care. The prominence of health and medical research organisations and their close links to the health care sector create an expectation in the public that all the healthcare they receive is safe, effective and evidence based.

Research Australia's members work hard to contribute to an evidence-based healthcare system that is continually improving the healthcare delivered to patients. This is achieved through the development of new treatments based on scientific evidence which have been rigorously tested and evaluated to ensure they are safe and effective.

This necessarily relies on access to information about individuals' health and wellbeing, and data about the treatments being received and the medications used. Improving the health and wellbeing of Australians was identified by the Productivity Commission as one of the greatest gains that could be achieved from better sharing of Public Data.⁷

Research Australia is supportive of the current direction for the Data Sharing and Release legislation outlined in the Discussion paper. We hope that our submission in respect of the framing of the legislation is helpful and look forward to contributing to the further development of the legislation in any way we can.

⁷ Productivity Commission 2017, *Data Availability and Use*, Report No. 82, Canberra, p.5-8, Appendix E

Appendix- R&D Tax Incentive definitions

The Australian Government provides tax incentives for certain Research and Development activities. To distinguish between R&D activities that are eligible for the Research and Development Tax Incentive (RDTI) and those that aren't, the Income Taxation Act 1997 defines both 'core' and 'non core' R&D activities.⁸

(1) **Core R&D activities** are experimental activities:

- a. whose outcome cannot be known or determined in advance on the basis of current knowledge, information or experience, but can only be determined by applying a systematic progression of work that:
 - i. is based on principles of established science; and
 - ii. proceeds from hypothesis to experiment, observation and evaluation, and leads to logical conclusions; and
- b. that are conducted for the purpose of generating new knowledge (including new knowledge in the form of new or improved materials, products, devices, processes or services).

(2) However, none of the following activities are **core R&D activities**:

- a. market research, market testing or market development, or sales promotion (including consumer surveys);
- b. prospecting, exploring or drilling for minerals or petroleum for the purposes of one or more of the following:
 - i. discovering deposits;
 - ii. determining more precisely the location of deposits;
 - iii. determining the size or quality of deposits;
- c. management studies or efficiency surveys;
- d. research in social sciences, arts or humanities;
- e. commercial, legal and administrative aspects of patenting, licensing or other activities;
- f. activities associated with complying with statutory requirements or standards, including one or more of the following:
 - i. maintaining national standards;
 - ii. calibrating secondary standards;
 - iii. routine testing and analysis of materials, components, products, processes, soils, atmospheres and other things;
- g. any activity related to the reproduction of a commercial product or process:
 - i. by a physical examination of an existing system; or
 - ii. from plans, blueprints, detailed specifications or publically available information;

⁸ Income Tax Assessment Act 1997 - Section 355.25

- h. developing, modifying or customising computer software for the dominant purpose of use by any of the following entities for their internal administration (including the internal administration of their business functions):
 - i. the entity (the **developer**) for which the software is developed, modified or customised;
 - ii. an entity connected with the developer;
 - iii. an affiliate of the developer, or an entity of which the developer is an affiliate.

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