



aamri

Association of Australian
Medical Research Institutes

SUBMISSION TO

**BOOSTING THE COMMERCIAL RETURNS
FROM RESEARCH DISCUSSION PAPER**

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ABOUT AAMRI

AAMRI is the peak body representing medical research institutes (MRIs) across

Australia. Our 45 member institutes are leaders in health and medical research, and collectively represent over 10,000 staff and students and an annual turnover of more than \$1 billion. The majority of our members are 'independent' MRIs, that is, mission-driven charities legally independent of a university or hospital, and co-located with a hospital or healthcare provider. The remainder of our members are university- or hospital-based institutes, or an alliance of research partners.

Australia's MRIs work on an extensive range of human health issues, from preventative health and chronic disease, to mental health, Indigenous health and improved health services. Their research ranges from fundamental biomedical discovery through to clinical research and the translation of research findings from bench to bedside. Together, they aim to drive innovation in healthcare to improve the lives and livelihoods of people in Australia and world-wide.

INTRODUCTION

AAMRI welcomes the review of Government mechanisms to boost the commercial returns from research. As outlined in our submission to the **STRATEGIC REVIEW OF HEALTH AND MEDICAL RESEARCH** on enhancing the commercial outcomes of health and medical research (**Appendix 1**), there is a range of factors contributing to Australia's poor track record in translating research into commercially viable products and services.

AAMRI sees the Commonwealth Government having a clear role in facilitating the commercial translation of research by:

1. using funding and policy levers to motivate, support and upskill publicly-funded research organisations to drive research commercialisation;
2. providing targeted financial support to de-risk areas of market failure in the commercialisation pipeline, closing the gap (or the 'valley of death') between research discovery and investor interest in commercially-relevant intellectual property (IP);
3. delivering facilities and programs that facilitate engagement between industry and research organisations; and
4. providing a regulatory and policy framework where industry flourishes and commercial investment in research is encouraged.

There is a concerning focus of the Boosting the Commercial Returns from Research discussion paper on policies and schemes that encourage research-industry 'collaboration' as the major Government lever to improve research commercialisation. While we acknowledge that Australia ranks poorly compared with our OECD counterparts in industry-researcher collaborations, we also rank poorly in other innovation metrics such as new-to-market and new-to-world patents, and high technology / medium-to-high technology exports. The reason for the low level of engagement between Australian business and research organisations is not simply the result of insufficient Government funding or incentives to directly encourage this. It is an indicator of a much more complex system of issues (including a predominantly low-tech and risk-averse industry base to begin with, a lack of experts in commercialisation and product development, and a paucity of venture capital funding to support the spin out of new innovative businesses), all of which must be considered in improving the commercial returns from research.

Recent initiatives in the Commonwealth Government's **INDUSTRY INNOVATION AND COMPETITIVENESS AGENDA**, such as the proposed regulatory changes for Employee Share Schemes and for the approval of medical devices by the Therapeutic Goods Administration, are positive developments for supporting innovative industries in Australia. These industries, in turn, are more likely to invest in research, employ researchers, and collaborate with research organisations.

While the discussion paper's proposals to recognise and reward industry experience, upskill researchers, and increase industry access to research have merit, they do not address the key enduring barrier to the commercial translation of research: limited access to finance (both for research organisations and businesses) to get potentially valuable research discoveries or IP to a point where there is commercial interest in investing in them. This funding bottleneck in the commercialisation pipeline has been exacerbated by the recent reduction in Commonwealth Government funding for research commercialisation activities, and the axing of the Innovation Investment Fund (IIF).

Valley of Death 1: Funding for proof-of-concept experiments and early IP protection

An early step in research commercialisation is building compelling proof-of-concept data necessary to prove (or otherwise) that a discovery or concept is commercially viable so that it can then attract early-stage private investment or industry interest.

A significant funding gap for proof-of-concept research and early-stage protection of ensuing intellectual property (IP) prevents potentially valuable discoveries from making it out of research institutions and into the market place. While NHMRC Development Grants support proof-of-concept research, this scheme represents less than one per cent of total NHMRC funding. Also, medical research institutes (and medical research) are not eligible for equivalent ARC funding schemes. There is also a paucity of funding for stage 1 clinical trials, whose successful completion is often necessary to attract investor interest. The NHMRC and ARC also forbid grant funds from being used to protect IP, meaning that there are literally no Government schemes to protect potentially valuable IP arising from Government-funded research. The result is that most research organisations are unable to adequately test the commercial viability of their work and protect potentially valuable IP.

We provide a model at Appendix 1 of how a scheme for proof-of-concept funding could be used to bring together sub-critical groups of commercialisation expertise across precincts or 'catchments' of research organisations (including universities, medical research institutes and hospitals) into larger, more viable commercialisation arms. These could be modeled on the successful Medical Research Commercialisation Fund and UniQuest (see Appendix 1), which would have the expertise and successful governance structures in place to administer new proof-of-concept funding.

Valley of Death 2: Seed funding and venture capital

*A lack of access to venture capital is a critical issue for Australian innovation. There is an opportunity for the Commonwealth Government to assist in attracting venture capital investments to Australia by supporting organisations similar to the Medical Research Commercialisation Fund and Uniseed, with a proven track record in attracting national and international third party investments by aggregating ideas and 'deal flow' into large enough catchments to become noticeable to external venture capital (see Appendix 1). For example, by subsidising administration costs, the Government could enhance the attractiveness of these organisations as an investment, including for the superannuation industry. The 'Translational Biotech Fund' recommended in the *Strategic Review of Health and Medical Research* is another model by which the Government could increase the availability of seed funding and venture capital.*

In the case of health and medical research, these valleys of death might be addressed by some of the proceeds from the proposed Medical Research Future Fund (should it come to fruition, albeit 8-10 years from reaching maturity). In the case of other research areas, a separate sovereign fund could ideally ensure secure, long-term funding to support the commercial translation of research and innovative industries. In the shorter term, a re-allocation of the limited funding that currently exists for commercialisation and research-industry linkages should be considered in all areas of research.

A failure to address the above funding bottlenecks will mean that potentially valuable IP will continue to sit inside research organisations out of reach of the investors, industries and markets that could benefit from them. We urge that these valleys of death be addressed when considering Government mechanisms to boost the commercial returns from research, along with the below recommendations that refer to proposals raised in the discussion paper.

DISCUSSION PAPER PROPOSALS

1. Creating stronger incentives for research-industry collaboration

Recognising industry experience in assessing competitive research grant applications

Currently, industry and commercialisation outcomes are inadequately recognised in the professional recognition processes within which academic researchers work, including in the awarding of Commonwealth Government grants and fellowships. While commercial outcomes are represented in the assessment criteria of some grants and fellowships, there are no agreed metrics, and peer review panels rarely have the necessary expertise to assess commercial/industry outcomes. Consequently, the awarding of grants and fellowships are almost exclusively based on traditional academic metrics, and time spent by researchers in industry or undertaking activities that do not result in traditional publication outputs can be fatal to a researcher's career.

AAMRI supports the proposal to modify the peer review of competitive grants and fellowships to recognise industry-relevant outcomes. It is important that industry experience/outcomes are given equal value to non-industry research experience/outcomes (but without any negative consequence to applicants for not having industry experience). As such, applicants would not be penalised for a reduction in traditional academic outputs that result from time spent in industry and/or on activities involved in the translation of research, and commercial outcomes (e.g. IP generation, product development, funding/contracts with industry, clinical trials, etc.) would be taken into consideration in an applicant's track record.

We suggest that recognition of industry/commercialisation outcomes should be part of a broader framework that recognises research translation and impact (including non-commercial impact and adoption), such as that outlined by the MORIA framework (see section 5 below). Non-commercial translation and adoption of research findings is particularly common in the case of health and medical research (e.g. an improved clinical guideline or practice, not involving any new product, that reduces the time taken per patient or reduces hospital re-admissions).

Pivotal to the successful recognition of commercial outcomes in the peer review process will be the inclusion of commercial expertise on all NHMRC and ARC grant review panels. The inclusion of industry outcomes in the assessment criteria of grants and fellowships alone will not have any affect if these cannot then be appropriately assessed.

Finally, institutions where industry experience and commercialisation skills are clearly available should also be encouraged. Research is increasingly a whole-of-enterprise exercise, and the assessment of research grants should recognise that, just as access to excellent core research facilities makes a grant more feasible, so too does access to industry connections and commercialisation expertise.

Rewarding end-user engagement in the funding of research block grants

Universities receive block grant funding through four different Government schemes administered by the Department of Education – Research Infrastructure Block Grants (RIBG), Sustainable Research Excellence (SRE) Scheme, Joint Research Engagement (JRE) Scheme, and Research Training Scheme (RTS). Together, through a complicated mix of formulae, these schemes provide funding for the indirect costs of research associated with

Australian Competitive Grants, and also reward research excellence and the attainment of funds from alternative sources (including industry).

Medical research institutes (MRIs) are not eligible for these research block funding schemes, but instead receive 20 cents per dollar of NHMRC grant awarded to meet the indirect costs associated with these grants through the NHMRC's Independent Research Institutes Infrastructure Support Scheme (IRIIS). Unlike universities, they do not receive any Commonwealth Government funding to reward excellence, industry engagement, or funding attained from alternative sources. Some (but not all) state and territory governments provide some funding to MRIs to assist with indirect research costs and/or to reward excellence and innovation.

In principle, AAMRI supports an allocation mechanism for research block grants that rewards research organisations for engaging with end-users and industry. However, care must be taken to avoid perverse incentives and gaming of the system. The allocation framework should recognise a wide range of commercial adoption (beyond just product sales), including translation of research that doesn't involve an industry partner (e.g. in cases where the end-user is a hospital or government department), or that is via a non-traditional commercialisation pathway (e.g. some research can go direct to market without an industry partner, such as in the case of health apps and websites, which are becoming increasingly common outputs of health and medical research).

We also recommend that in rewarding engagement with end-users and research translation, that universities not be considered in isolation, but that MRIs (whose indirect costs are funded through different mechanisms) also be considered. Therefore, the university-based block grant system might not be the most appropriate scheme (or certainly not the only scheme) to reward end-user engagement across the sector.

Leverage greater collaboration between industry and research organisations

Examples worldwide (e.g. Singapore, Ireland) show that research excellence acts as a major attraction for industry as the focus for outsourced research. Therefore, the Government's continued long-term support for research is key in attracting industry investment in research.

We re-iterate the importance of improved funding for proof-of-concept experiments (with or without an industry partner) and funding for early-stage IP protection in order to get research discoveries to a point at which industry is interested in being involved. We recommend that NHMRC Development Grants, which support proof-of-concept experiments, be made available in a more timely and rapid manner, rather than through the current annual process. The proportion of the NHMRC grant budget allocated to Development Grants, currently less than 1 per cent, should also be substantially increased.

The ARC Linkage Grants supports collaborative research of universities with industry and other end-users. However, these grants are not open to health and medical research, or to MRIs. We recommend that an equivalent scheme be implemented under the NHMRC to promote industry-researcher collaborations.

There is also the opportunity to increase meetings and networks between industries and research organisations. Currently industry does not know of the possibilities for collaboration and the researchers do not know of the interesting possibilities available in industry, including opportunities for joint projects. Incubator units are also not readily available for start-up or micro-companies.

Caution should be exercised in transferring successful industry-research programs from overseas to Australia. The small size and geographical dispersion of Australian industry, the predominance of low-tech and risk-averse industries, and the remoteness from key foreign markets mean implementing innovation schemes from other countries is unlikely to result in the same success here. Adapting well-regarded existing Australian schemes is more likely to succeed.

Consolidation of programmes that encourage research-industry collaboration

AAMRI urges caution in consolidating existing programmes that encourage research-industry linkages. While consolidation would provide greater scale of funding for any remaining program, the unique and complementary roles each of the current programmes plays in improving research-industry links and the commercial translation of research should not be overlooked.

Several programs facilitate research-industry linkages in different ways and contexts:

ARC Linkage Grants support collaborative research of higher education providers with industry, end-users or other parts of the innovation system in order to translate and apply research to a specific problem or opportunity at the individual project level. *NHMRC Development Grants* provide funding for early proof-of-concept research, which if successful, may result in a partnership or license deal with industry.

The Entrepreneurs Infrastructure Programme (EIP), through the *Research Connections stream*, specifically targets SMEs to engage a research organisation in a 'research service provision' role to tackle a knowledge gap or barrier at a relatively small scale and short time-frame. This is distinct from projects supported by ARC Linkage Grants, which are collaborative in nature and are targeted at translating discoveries arising from university-driven research, rather than facilitating business-led research.

The CRC Programme – with its much larger scale of funding, longer timeframes and networks of partners – brings together a critical mass of multi-disciplinary partners to meet an industry's research needs to tackle a major barrier or capitalise on a significant opportunity for improved products, services or outcomes. Importantly, the programme is also open to non-commercial sectors, including government services, health service providers and the non-profit sector. Unlike ARC Linkage Grants, which tend to capitalise on an opportunity to apply research to a specific problem, these grants are industry or end-user led, and are much bigger in scale than the aforementioned programmes, and thus tackle different scales of issues/opportunities.

Industry Growth Centres are intended to improve the competitiveness and productivity of industry sectors in which Australia has a competitive strength, including through the delivery of large-scale collaborative projects. Unlike the above initiatives, this programme is targeted to address sector-wide barriers and opportunities, and has a much broader remit in building capability, reducing regulatory burden, and providing a 'competitiveness roadmap', as well as supporting collaborative R&D and commercialisation projects that have broad sector-wide implications. Importantly (and worryingly), these centres will be expected to be self-sustaining after four years. It is not clear at this stage how this programme relates to the ARC's Industrial Transformation Research Programme.

Each of these programmes, with its different eligible organisations, scales, and breadth of

activities, plays a unique role in building links between research organisations and industry.

Rather than consolidating programmes, we suggest that the introduction of the new Industry Growth Centres and the current review of the CRC Programme be used to clearly define the unique roles of these programmes, adapt them if necessary, and at the same time, improve their agility and flexibility to encourage industry involvement. The lack of stable, long-term initiatives to support commercialisation and research-industry links has significantly hampered industry involvement in these Government programmes in the past. The sudden axing of the Commercial Ready program in 2008, and the more recent termination of Commercialisation Australia without notice are cases in point. The Government should avoid perpetuating this issue.

Role of R&D Tax Incentive in encouraging research-industry collaboration

The R&D Tax Incentive is a key Government lever in stimulating business investment in research by de-risking this investment. There have been positive developments to the scheme to tighten up research definitions and encourage research investment by SMEs. *However, changes to specifically encourage (or force) the collaboration of industry with research institutions has the potential to damage the programme* by increasing red-tape, encouraging gaming, reducing flexibility, decreasing the scheme's attractiveness and uptake by industry, and ultimately reducing the ability of the R&D Tax Incentive to meet the needs of industry.

2. Supporting research infrastructure

AAMRI strongly supports a long-term investment in research infrastructure for publicly-funded research organisations and industry modelled on the highly-regarded National Collaborative Research Infrastructure Strategy (NCRIS). Successful elements of the programme that should be emulated in any future scheme include:

- leveraging of investment from state and international counterparts, and potentially also industry partners;
- funding towards facility operational costs, including specialist personnel, for superior service delivery and research outcomes;
- the use of a strategic, highly consultative roadmap approach to meet Australia's infrastructure needs; and
- provision of services free of charge (or at cost) for publicly-funded research organisations to avoid cost-shifting and unnecessary red tape, while charging industry a fee-for-service.

3. Providing better access to research

Strengthening IP guidelines for researchers, and linking research funding to IP dissemination

AAMRI endorses the national principles for IP in public institutions. These are a sensible guide that provide the opportunity for entities to decide if the public interest is best served by, for example, licensing or open access to IP.

We urge caution in regulating the dissemination of IP arising from Government-funded research (presumably applicable to provisional patents that have not been converted to PCT patents after a fixed period). Increased regulation and red tape around IP has the potential to discourage the protection of potentially commercially-relevant research findings, and inadvertently encourage more traditional academic pathways of research. The significantly

longer timeframes and more costly pathways required for the commercial translation of health and medical research (including tests in animal models and clinical trials) could also cause problems for any broad-based IP policy.

If the purpose of requiring the dissemination of IP is because the Government is of the view that potentially valuable IP is not being exploited by research organisations, then we suggest investigating why this is the case. Reasons might include the lack of Government funding for early-stage proof-of-concept experiments necessary to progress IP, the inability to use NHMRC and ARC grant funding to protect IP, an inability to secure seed funding, or a lack of access to the skills necessary to pursue IP. Alternatively, an unexploited patent might mean the IP is not of any value, meaning requiring its dissemination could be an unnecessary administrative burden.

It is generally acknowledged that provisional patents are filed on far too much non-commercialisable IP (in Australia and world-wide). This over-proliferation of provisional patents can in turn make securing the rights to all the relevant IP needed to convert genuine provisional patents to PCT patents difficult. We agree that, in principle, this could be overcome by ensuring patents based on publicly-funded research that potentially block the development of other patents, but that have no commercial value in their own right, are freely available. However, such a policy in Australia would have very little effect here, as the majority of Australian patents are blocked by international provisional patents.

Establish an online point of access to commercially-relevant research for business

While the establishment of an online point of access to commercially-relevant research for business appears logical in principle, we believe it would be a costly exercise with limited success. University tech transfer offices and other organisations such as the Medical Research Commercialisation Fund (MRCF) already provide this service tailored to the strengths, objectives and business models of their own organisations (e.g. contract research versus collaboration versus IP licensing, etc.). A Government-funded website would duplicate these other resources, require significant resources to maintain, and would face substantial hurdles in keeping the database up-to-date and getting research organisation buy-in. This model also overlooks the competitive nature of universities and other research organisations in attracting businesses to their research services. Research organisations also get much more out of their own web-based resources, which are tailored and flexible, provide important analytical information on web traffic, and direct external stakeholders to their organisations.

Industry access to research or research expertise (whether in the form of a consultation service, collaboration or interest in the commercialisation of a technology) also requires a tailored service, including localised knowledge, specialised skills, and personal follow up, which would not be provided by a central website resourced by government.

We suggest that a more productive role for the Commonwealth Government would be to provide links to the various websites of research organisations where this information and services are already available.

Whole-of-Government policy to open up access to publicly-funded research

The current policies of the NHMRC and ARC to make the results of research publicly available within 12 months of publication are sufficient and meet international standards of open access to research. These recent policy changes have resulted in a significant

administrative burden on research organisations, many of which are still putting in place the necessary processes to meet the new requirements. We do not recommend any additional policy requirements at this stage; any future changes should first require an assessment of the effectiveness of the open access policy reforms to date in improving access to research.

IP toolkit to simplify negotiations relating to IP between researchers and industry

An IP toolkit could have some limited use to research organisations, depending on what it included and the level of industry input into its development. However, the key to simplifying negotiations relating to IP is for the partners to the contract to have access to accurate professional advice, and fair evaluation and valuation of the IP. Australia lacks skilled experts in IP evaluation and valuation. *Therefore, more important than an IP toolkit is funding to access professional advice (for example, through small grants from the Entrepreneurs' Infrastructure Programme), including the potential to import talent on a case to case basis.*

4. Increase industry relevant research training

AAMRI supports changes in research training arrangements requiring a commercialisation component in PhD programmes. An excellent example of a low-cost, valuable programme is the former commercialisation 'boot camp' run by IMBCom, previously mandatory for all PhD students at the Institute for Molecular Bioscience (UQ).

We also support the provision of more intensive professional development programmes aimed at skilling up early- to mid-career researchers. However, the insufficient funding of research organisations for the indirect costs of research means that the provision of such programmes is difficult.

The CRC Programme is arguably the most cost-effective and useful Commonwealth Government scheme at providing intensive skills in how to operate with industry. Such skills and experience are extremely valuable in bringing about bottom-up cultural change and developing future leaders in industry-research links. However, only a small number of researchers access the CRC programme, and other more generalised schemes are needed to ensure a broad industry/commercialisation understanding and skills across the research workforce.

In the health and medical research sector, the NHMRC Career Development Fellowship scheme aims to build researcher capability in industry skills. However, in 2014, the NHMRC funded just two new Industry Career Development Fellowships.

An excellent example of an independent professional development programme aimed at early- and mid-career researchers is the [Molecules to Medicine program](#), sponsored by the Victorian Government and open to all Victorian biomedical research organisations.

5. Measurement of outcomes

Any new metrics to measure (and reward) the commercialisation/translation of research should also capture non-traditional pathways of research translation. The translation of certain types of research (such as the uploading of an app to iTunes, a website resource, or open access software) may not require licensing of IP or even an industry partner to go to market. Some MRIs also have subsidiary companies that coordinate clinical trials or clinical genetics services and act as their 'internal industry partner'. We strongly recommend against the use of simplistic commercialisation measures such as the number of patent applications and families.

Also, measurement of knowledge transfer and engagement with industry should be considered in the broader context of the many other pathways to research impact, including engagement with end users from other sectors. In many cases this engagement can still result in direct or indirect economic impacts, as well as other public good outcomes. Examples include translating research findings into improved guidelines for clinical practice, new methods to improve the cost-effectiveness of health services, and policy advice to government agencies or not-for-profit organisations (e.g. in emergency services, health policy, improved community service provision, etc.). In such cases, the level and breadth of impact (local, national, international adoption) should be considered in comparing metrics.

Should measurements of impact/outcomes be implemented, we suggest consideration of the Measurement of Research Impact and Achievement (MORIA) framework, which was developed by a working group of the NHMRC several years ago as an analytic instrument in the peer review process, but was never implemented. Intended for the health and medical research space – but adaptable to other research areas – the MORIA framework looks at outputs (or ‘activity’), outcomes (or ‘recognition’) and ‘impact’ of research across three domains: knowledge, health gain and economic benefits. Importantly, the framework uses a scoring system that translates information into a standardised numerical score to allow the comparison and aggregation of findings across the three measurements and the three domains.

6. Capitalising on the Medical Research Future Fund (MRFF)

AAMRI strongly supports a role for the MRFF in boosting the translation and application of health and medical research discoveries into new and improved medicines, devices, policies and practices that have a direct impact on health outcomes, drive behaviour change and create a more effective, productive health system.

Beyond the suggested support for “collaboration between researchers and industry”, we suggest that the MRFF be used to drive both commercial and non-commercial translation and implementation of health and medical research findings. This would include improved funding for proof-of-concept research, clinical trials, implementation research, IP protection, commercialisation activities and seed funding (such as the ‘Translational Biotech Fund’ recommended in the *Strategic Review of Health and Medical Research*). The MRFF could also help embed research in health services (the ‘end users’ of findings from health and medical research), including through funding for health services research, health economics and health policy research.

However, we urge caution in relying on the MRFF to boost the translation of health and medical research in the current Government strategy. It is not yet clear whether legislation for the MRFF will be passed in Parliament, nor what size the MRFF will be at full maturity. Further, even using current Treasury projections, the MRFF will not reach maturation until 2022-23, with only an additional \$22 million in disbursements for health and medical research in 2015-16, increasing to \$77 million in 2016-17.

7. National research priorities and targeted research effort

AAMRI supports the Government’s industry innovation strategy of building capacity and driving private research investment in areas of competitive strength and national priority. The focus of the new Growth Centres on five priority industry sectors is a good example of this. This can work well as long as there is flexibility to incorporate emerging industries in the future, and there are other broad-based sources of funding that ensure that as a nation we

capitalise on innovative ideas of high potential from other industry sectors (e.g. by ensuring that the Entrepreneur's Infrastructure Programme is open to all industries, with funding based on merit). Excluding businesses from outside these five focus industry sectors from any source of funding to commercialise ideas could mean important discoveries and industries of the future go offshore where commercialisation and industry innovation is more broadly supported.

We also support the allocation of a certain percentage of Government funding for research towards meeting identified national needs and opportunities, as suggested in the discussion paper. Good examples of this include the quarantining of a percentage of NHMRC funding for Indigenous research, and NHMRC Targeted Calls for Research (e.g. in mental health research, avian influenza, hendra virus). However, while it is important to identify and address gaps in research that mean national needs or opportunities are not being met, we recommend against all research having to fit under a national priority in order to be funded. To do so would either eliminate funding for highly valuable research that does not meet a national priority, or would mean that the national research priorities would have to become so broad as to deem them useless.

In the publicly-funded research sector, targeted research must be balanced with other applied research and cutting edge frontier research. It is simply not possible to know from which area of research the next biggest Australian innovation is going to come. Indeed, some of Australia's most ground-breaking innovations have come from basic research that meets no obvious national need (e.g. Wi-Fi technology). It is essential to maintain some non-targeted research that is awarded purely based on merit. This allocation of some research funds based on national priorities/need and some based on merit is consistent with recommendations of the *Strategic Review of Health and Medical Research*.

MEMBER INSTITUTES



