

Improving Knowledge Exchange & Shortening the Innovation Pipeline

Report from Research Workshop

13 December 2018 The British Embassy, 3100 Massachusetts Ave NW, Washington, DC 20008, USA



www.star-idaz.net

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Introduction

Animal diseases can cause serious social, economic and environmental damage, impact on animal welfare and in some cases directly threaten human health. STAR-IDAZ International Research Consortium (IRC) on Animal Health is a network of 25 research-funding organisations from 18 countries. The overall objective of the IRC is to coordinate research at the international level to contribute to the development of new and improved animal health tools and strategies. To achieve this, a systems approach to the development of animal disease control strategies, based on integrated research roadmaps, has been adopted. The system has been designed to focus research efforts on the critical gaps. This systems approach also aims to capture the wider collaborative cross-sector requirements and solutions for global animal disease control.

The workshop held in Washington on 13th December brought together research programme owners and associated stakeholders from across the public and private sectors in the US to discuss how they can engage with the IRC's research roadmaps and move forward collectively to shorten the innovation pipeline to tackle animal disease in the livestock sectors.

Talks and presentations

A number of presentations were given on the day to set the scene for the group discussions that followed and these, listed and linked below, are available from <u>www.star-idaz.net</u>:

- 1. Animal Production and the Environment, Ed Topp
- 2. Encouraging Research to Combat AMR the Role of the OIE, Stefano Messori
- 3. <u>Prioritization of Diseases for which Vaccines Could Reduce the Antimicrobial</u> <u>Use in Animals, Cyril Gay</u>
- 4. <u>Ecology and Evolution of Infectious Diseases A US-UK Bilateral Funding</u> <u>Initiative, Sadhana Sharma</u>
- 5. <u>ERA-net Co-fund on Animal Health Platform for an International Joint</u> <u>Funding Initiative, Scott Sellers</u>
- 6. Overview of STAR-IDAZ IRC, Alex Morrow
- 7. Via Making system innovation happen, Chris Thompson
- 8. <u>Introduction to IRC Research Roadmaps Vaccines, Diagnostics,</u> <u>Therapeutics, Epidemiology and Control, Luke Dalton</u>



Foreword by Professor Dame Sally Davies

Research and Development (R&D) is one of the areas in addressing AMR that I am most passionate about so it is great to see so many research funders and experts in the room to discuss supporting further R&D in animal disease control and to improve coordination and collaboration: while some duplication in science is needed we need to maximise the impact of our investments as resources are scarce.



We must also align with the Sustainable Development Goals and other agendas such as Global Food Security, climate change, and Universal Health Coverage (UHC). I was pleased to see the

systems and interdisciplinary approaches being taken by STAR-IDAZ as infections and AMR are complex and interconnected with so many other issues including the role of the microbiome coming into play. I am pleased to see that Industry are part of STAR-IDAZ efforts, helping to join up the innovation pipeline.

We must also use an "AMR lens" on all of our investments like we do for gender and climate change. I urge you all to think about how you could implement and monitor that in your organisations.

We must ensure funders are investing across basic, applied, clinical and operational research. I was pleased with U.K. investing £8.2m through the Department of Health in AMR applied research with TDR: We need more of this.

The goal is to prevent infection so AMR-sensitive projects such as the Gates-funded "reinvent the toilet" on safe disposal of human waste will go a long way to reduce infection and AMR in the developing world.

We not only need to invest in R&D in our own countries but also in LMICs, for example to:

- address the global problem where it will have the greatest impact
- show solidarity in a shared challenge
- protect our population economic consequences, Global Health Security (GHS), biosecurity
- provide needed data to understand the threat further and in other contexts in order to contain and control disease
- balance self-interests and corporate/social responsibilities

The GAMRIF (Global Anti-Microbial Resistance Innovation Fund) project has now committed all of its £50m, including with partners in the room - US, Canada, Gates, Wellcome, and although based at the Department of Health and Social Care, it had to be One Health so around £20m of this fund has gone to animals and environment research and leveraged further funds from partners - so we can do more together to support LMICs.



We also need to evaluate more:

- I. impact from investment
- II. sustainability
- III. what works, or doesn't work and why

The AMR lens should be used more to ensure that there are no unintended negative consequences, while trying to do good. We need to think more about the long term consequences and less about the short term gains - it is why we are in this mess with AMR, and we need to understand different funders incentives and prioritise better.

I urge countries and funders to increase coordination efforts domestically to be able to fully contribute internationally; in the UK we have the AMR funders forum which feeds into the U.K. efforts in international programmes such as the Joint Programming Initiative on AMR (JPIAMR) and STAR-IDAZ. And while the IACG develop their recommendations that all are waiting for we then need to wait for them to be taken forward and implemented; it is refreshing to see you all here today just getting on with the business!

We have disinvested in this area for over 20 years, it will take that and more to reinvest and contain and control infections and AMR so we must do this in a sustainable way and make it our "business as usual". We cannot become complacent and we need to learn from our mistakes.

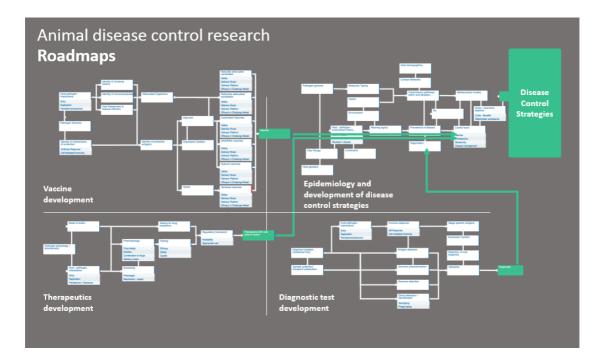
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Professor Dame Sally Davies, Chief Medical Officer of England and Co-convener of the United Nation's Interagency Coordination Group on Antimicrobial Resistance (IACG)



Overview of the IRC Research Roadmap System

A set of generic research roadmaps have been created for the development of 1) candidate vaccines, 2) diagnostic tests, and 3) therapeutics to be applied to a number of priority animal diseases. These development pathways for disease control tools are integrated into a fourth (overarching) roadmap: 4) Epidemiology and Development of Disease Control Strategies. Presented in a way not dissimilar to a flow-chart with the defined end product/solution located on the right, they provide a way of visualizing complex problems and breaking them down in manageable components by mapping out all of the significant steps that have to be taken and problems that have to be solved in order to deliver the tools or strategies required.

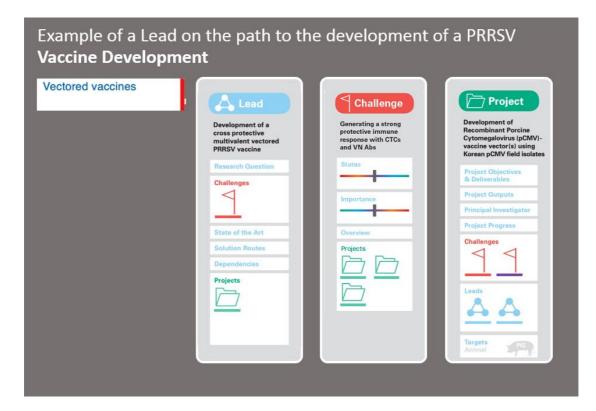


The steps in the roadmaps are referred to as 'leads' with each one representing a body of scientific knowledge outlined by a Research Question ("What are we trying to achieve?", "What is the problem we are trying to solve?") and broken down into more specific:

- Challenges ("What are the scientific and technological challenges/Knowledge gaps needing to be addressed").
- Possible Solution Routes ("What approaches could/should be taken to address the Research Question?").
- Dependencies (What else needs to be done before we solve this need).
- State of the Art (Existing knowledge including success and failures).



Having identified the critical gaps through this process, the next step is to map details of current research projects onto the specific Challenges to assess the extent to which they are already being addressed. Links to project outputs, including underpinning data, will also be captured in the System as will the details of research-funding and research-providing organisations (including research capacity) linked to the projects. Critical Path Analysis will effectively highlight the bottlenecks and identify the research areas along the roadmaps that are most in need of further effort and investment.



The STAR-IDAZ IRC partners, as research funders and programme owners, will endeavour to align their research programmes in order to address the research gaps identified in the roadmaps.



Summary of discussions

The full readouts of the breakout group discussions and list of participants are included in annexes 1 and 2 respectively.

- 1. Workshop participants comprised research programme owners from the public and private sectors and representatives of associated stakeholder groups. They were split into the following breakout groups to discuss the IRC roadmaps, to look at how they can engage with them and identify the challenges involved in doing so:
 - I. Animal health and livestock industries
 - II. Research institutions
 - III. Public funders: Government
 - IV. Research councils and charities

The highlights of these discussions are combined and summarised below with the full readout available in Annex 1 of this report.

Perceptions of various stakeholder groups of the Research Roadmaps and the challenges relating to data capture and engagement with them

The roadmaps are useful for focussing gap analysis and in prioritising actions but must consider the social, financial and regulatory barriers to developing new control tools. Consulting the end users early in the process such as when defining the Technical Product Profiles (TPPs) would help with this. The roadmaps and TPPs will need to be updated regularly to ensure that they remain relevant.

Having a common language and framework is useful as is knowing where efforts are being focussed along the research pipeline and who else is working on specific areas. Researchers are already aware of where the gaps exist but may not be aware of areas to which no research effort is being directed. With research infrastructure mapped through the system and underpinning research data made publicly available in a standardised format, the system could provide significant value but industry should help to define the standards that are required for data to be of use to them as end users. Provision of open and accessible data is desirable from public funders but it would be good if it was possible to track who was accessing and using the data (traceability).

The roadmaps will be useful to funders in supporting strategy development but their limitations need to be recognized; the roadmaps are a component of the work required to develop and justify a strategy, but donors still need to engage with committees and consultants to develop the final approach that will be adopted by their leadership. Sufficient industry engagement is necessary to achieve a practicable product, particularly through involvement in developing TPPs. It was also noted that regulators should be engaged early on to kill off possible products and technologies that are not going to be taken forward. The

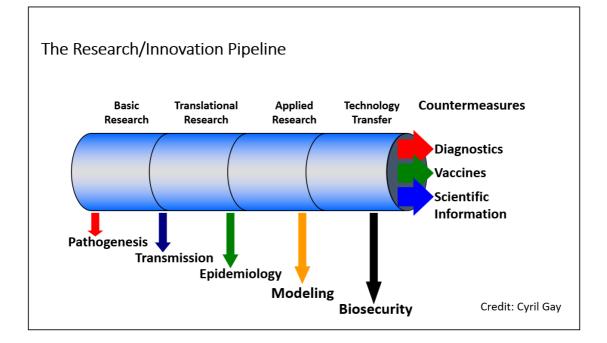


research priorities also need to be vetted but as they are likely to be published by the various Working Groups this is effectively covered.

A number of barriers were identified relating to adoption of the roadmaps as a tool to inform decision making and also to the provision of project data from research funders and providers. Barriers to adoption relate to their limitations including the fact that they are product focussed and may not go far enough in considering their uptake in the broader system. They could include research relating to regulatory systems and seek to provide evidence in support of changing regulations.

Key to the success of the roadmaps is the provision of project data by the research funders and research providers. A barrier to this is the time and effort required to provide it. Researchers may not be willing to share unpublished results so up-to-date data may not be captured i.e. the "publishing gap". There are limitations around IP, or sharing business sensitive data which restricts the level and degree of engagement. It was learnt that it will never be possible for the Animal Health industry to share details of most of the in-house research that they are conducting although it may be possible to share details of some precompetitive up-stream work. It is also very difficult for research bodies in the US to collaborate internationally and to accept people in their lab. They cannot release technology to some other countries such as those perceived as security threats so collaboration through the IRC may be more useful for research funders.

2. Following the breakout group discussions, participants were brought back together to discuss how they can work better together to shorten the innovation pipeline.





The highlights are summarised below with the full readout available in Annex 2 of this report.

General discussion on barriers to working together and how the Innovation Pipeline might be shortened

Barriers to working together

- A. Competition: Disease control technologies is a competitive area between companies and countries so there are limitations to the extent to which working together possible.
- B. IPR and Freedom to Operate:
 - Early engagement with industry is important in ensuring their early work and outputs are free of IP issues and suitable for commercial purposes.
 - IPR issues can increase the cost of producing vaccines. The more organisations involved in the process means more IPR costs and the complexity increases further across country borders.
 - Negotiating access to required adjuvants etc can be more costly and trouble than developing or using alternatives. Also, researchers can make the mistake of using a reagent which is already bound by IP obligations which means they are tied to them.
 - Laboratory kits available for purchase can be used to generate data but the data can be owned by the kit producer so the licencing agreement would need to be bought out by the industry partner. Academia therefore need to be open on their methodologies.
- C. Market potential and suitability: Researchers first need to establish from the pharmaceutical industry what they need with regard to its potential use in the target host species, cell line etc and whether there is a market.
- D. Early development costs: The problem in animal health is that a lot of the 'easy' research has been done so academia need to add value to the research process. They need to foot some early development costs in terms of technology transfer to attract industry involvement.
- E. Regulatory issues: It was suggested that GMO will be the new main regulatory issue. GMO vaccines can get licenced but this can be difficult and may not be acceptable in some countries/regions.

Challenges and ways to shorten the Innovation/Research Pipeline

- A. Investment in basic science:
 - Unless this improves then the research pipeline will be stifled. Immunology in particular is underfunded. Pharma companies do still undertake basic science but fewer of them now do it. Should government address this?
 - Long term issues and diseases such as ASF require investment in basic research e.g. gene function because it hasn't been done before.



- B. A systems (biology) approach:
 - There are currently too many specialists. More veterinarians should be encouraged to do PhDs.
 - One Health should be considered as part of the systems approach. The STAR-IDAZ IRC Working Group on Coronaviruses is bridging the gap between the veterinary and human sides by working with ZAPI. It is easier if we focus on those viruses that are currently a problem to both.
- C. Training and bringing people together:
 - The universities need (funding) to offer programmes with a systems approach.
 - Early exposure of young scientists to commercial and regulatory processes is invaluable.
 - Texas A&M's 'Bench to Shop' programme is very useful and more of this should be encouraged. It "enables 21st century researchers (graduate students, post-doctoral fellows, and/or early career faculty) to plan, execute, evaluate, and transition Transboundary Animal Disease (TAD) research technologies to the global marketplace".
 - Hold more workshops such as this bringing together all the different stakeholders and people along the research pipeline including pharma, regulators and diagnostics people.
- D. Incentives for industry: Academia can offer first right of refusal.
- E. Standardised Challenge Models would be very useful but they need to consider different host genetics and replicate the 'field situation' if being applied to global issues.
- F. TPPs:
 - It would be helpful if the Target Product Profiles (TPPs) for vaccines, diagnostics and therapeutics are defined early on.
 - There are issues regarding low income settings, deployment of vaccines and market viability. Packaging and distribution of vaccines are considered in the Target Product Profiles (TPP) rather than the roadmaps.
- G. Harmonisation of global regulatory processes.
- H. Information management:
 - A database of current research is needed which also shows where current activity sits on the research pipeline. The IRC Roadmap System is aiming to provide exactly this but it is difficult to capture details of progress in current projects. Ideally, the research community would take ownership of their data in the system and ensure their current project information is up to date.
 - Details of research failures would be useful but it is difficult to capture this and it would be difficult to motivate researchers to provide the information what incentive do they have? Could funders push for them to provide this?



Conclusions

Investment in research, particularly basic research, is crucial if we are to develop the tools and strategies needed to effectively control animal disease and reduce the dependence of the livestock sector on antibiotics. It is important that we take a systems approach and consider the wider implications and influences shaping the area in which we operate including environmental and human aspects. Collaboration and cooperation between organisations and across sectors, countries and initiatives help us to get the most out of the limited resources we have in animal health and maximise the return on our investment. The Research Roadmap System developed by the STAR-IDAZ IRC provides the means for us to collaborate better, share information and work together towards the focused delivery of new and improved animal disease control tools and strategies such as vaccines which are an essential component in reducing reliance on the use of antibiotics.

The roadmaps are seen to be a useful tool in focusing gap analysis, prioritising actions and supporting strategy development but require well developed and regularly updated TPPs with early input from industry and regulators. It is important that the vaccine, diagnostics and therapeutics roadmaps are considered in the wider animal disease control strategy context. A vetting process of the research priorities identified in the roadmaps such as peer review and a refined process for their analysis would increase confidence in them. To be most effective, the roadmaps require the provision of research project data from the research community so the IRC will look at how best to reduce the time burden.

Both public and private research funders and programme owners were represented at the workshop so they discussed potential barriers to them working together. These included competition, IPR or Freedom to Operate and the suitability of early development work by academia to be built on and taken forward to market. Early engagement with industry is vital in reducing these barriers. Participants also discussed ways in which the research or innovation pipeline could be shortened. Taking a systems approach and bringing all the people along the innovation pipeline, including regulators, together at workshops and through training programmes such as "Bench to Shop" were identified as effective actions. Stakeholder engagement at every stage of the pipeline is essential to shorten delivery time of new disease control strategies and ensure that research effort is not wasted. Harmonisation of regulatory processes globally would facilitate international partnerships and having TPPs, standardised challenge models and good information management systems would also be positive measures.

In-country collaboration/coordination is important as well as international collaboration but on the international side, joint research calls as occurred between European countries under the EMIDA and ANIHWA ERA-Nets and between the US and the UK under the Ecology of Infectious Diseases Initiative are an excellent way of fostering international collaboration and creating critical mass, bringing together different skill bases to address problems. A new



International ERA-Net is currently being developed which countries outside Europe are welcome to join.

The research roadmaps for the various diseases will be available on the STAR-IDAZ IRC website at ww.star-idaz.net and any programme owners and funders who are not currently part of STAR-IDAZ IRC are encouraged to join.

Next Steps

In response to the outputs of this workshop, particularly the suggestions made in the group and plenary discussions, a number of 'Next Steps' have been identified for the STAR-IDAZ IRC and also the workshop participants:

For the STAR-IDAZ IRC:

- 1. Consult the end users of the roadmaps early in the process when defining the Technical Product Profiles (TPPs) taking into account issues such as Return on Investment for the production of vaccines, diagnostics or therapeutics or wider acceptability of control strategies as outlined in the Systems Solution Maps.
- 2. Facilitate the updating of the roadmaps and TPPs regularly to ensure they are kept relevant, valid and focussed on the right outcomes.
- 3. The IRC will look at ways to capture details of pre-competitive, upstream research from industry as access to later, in-house research will not be possible.
- 4. The IRC will look at ways to vet the research priorities, such as through peer review of the roadmaps, and further consider the process of analysing them.
- 5. The IRC will make a drive to populate the roadmaps with gap analysis and project data but may need to consider other ways of obtaining research project data, particularly pre-published data if, as suggested in the workshop, the research community is not forthcoming.
- 6. In support of wider system consideration, SIRCAH will look at developing a research roadmap for host genetics in relation to disease control and a roadmap for vector biology.
- 7. Draw attention amongst members to the <u>STAR-IDAZ Data Sharing Statement</u> and policy for <u>Open data, IP and early engagement with industry</u> and encourage uptake.

For workshop participants:

- 1. Consider joining the STAR-IDAZ IRC and, if interested, send the Letter of Intent to the Secretariat of the IRC (SIRCAH).
- 2. Send links to research project databases and details of current and planned research projects to SIRCAH.



Forward look

The IRC will continue to generate and populate research roadmaps for our current-priority diseases/issues focusing initially on brucellosis, PRRS, bovine tuberculosis, African swine fever, foot-and-mouth disease, helminthoses, coronaviruses and influenza. These will be published online at <u>www.star-idaz.net</u> as they become available. The IRC will modify the system to allow the research community to upload their own project data into the system so that it can be mapped onto the roadmaps to assess whether the research gaps are being addressed or whether they require further resource. In the immediate future, we are organising a reception at the Embassy of the European Commission in Beijing on the evening of 11 March 2019 and a one-day workshop on 12 March to discuss the research needs relating to African Swine Fever. The IRC partners (funders and programme owners) will then meet on 13-14 March to discuss and agree how research areas are taken forward.

Keeping in touch

The Secretariat to the STAR-IDAZ IRC (SIRCAH) would like to thank everyone for their valuable time and input. We would like to keep in touch and keep you informed of IRC activities and would welcome your involvement along the way. We send out biannual newsletters to keep our members updated and will add your details to the mailing list unless you tell us not to. We also keep our website information updated with current events, meetings and opportunities so please do not hesitate to get in contact at the email addresses below.

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Annexes

Annex 1: Readouts of breakout group sessions

Perception of various stakeholder groups on the usefulness of the Research Roadmaps and the challenges relating to data capture and engagement with them

Animal health and livestock industry participants

- 1. The vaccine, diagnostics and therapeutics roadmaps need to be seen in the context of the wider animal disease control strategy roadmap and not taken forward in isolation.
- 2. The end point of the roadmaps, be it the technical product profile for the vaccines, diagnostics and therapeutics roadmaps or disease control/eradication in the animal disease control strategy roadmap need to be defined early on with the "end" users, taking into account issues such as Return on Investment for the production of vaccines, diagnostics or therapeutics or wider acceptability of control strategies of disease control strategies as outlined in the Systems Solution Maps.
- 3. There is need to also develop a research roadmap for host genetics in relation to disease control.
- 4. Concerning the sharing of data along the research pipeline, underpinning data needs to be in a standardised format when uploaded to publically available sites following publication of research papers if it is to be of use for years ahead to users further along the pipeline. This should include all of the metadata relating to the animals used etc. However the algorithms used for data mining will belong to the data users. Industry should help to define the standards that are required for data to be of use to them as end users.
- 5. It will never be possible for the Animal Health industry to share details of most of the in-house research that they are conducting although it may be possible to share details of some pre-competitive up-stream work.
- 6. Harmonisation of regulatory processes globally would speed up the delivery of new disease control tools.

Research Institutions

- 1. It would be useful to map infrastructure, including biological collections.
- 2. Most research institutions values very highly the roadmaps for guiding their research, going from the bottom to the top and being able to identify where efforts are being focussed will be useful as it is important to have information about who is doing what on the different topics.
- 3. In some countries, research institutions are already aware of what the gaps are (they are the experts); in addition it is very difficult for research bodies in the US to



collaborate internationally; to accept people in their lab; cannot release technology to other countries (terrorist nations); more useful for research funders.

- 4. Need to consider social, financial and regulatory barriers to develop new control tools, else these would be useless
- 5. An important barrier to sharing information on existing projects is the time needed to do so.
- 6. Identifying areas where there are less efforts could be of use to researchers.
- 7. There is need to educate policy makers about the importance of AH funding.

Public funders: Government

- 1. Having a common language and framework is very useful.
- 2. The roadmaps are useful for gap analysis and helpful in prioritising actions.
- 3. A similar approach is used internally at the Defence Advanced Research Projects Agency (DARPA) for specific viruses but the IRC system goes beyond that. The DARPA system involves input from a range of disciplines to generate new and creative ideas to address research questions.
- 4. The roadmaps will need to be updated regularly to ensure that they account for the evolutionary pressures that a vaccine creates. As a pathogen evolves and a vaccine becomes less effective this should be fed back into the roadmap by redefining the TPPs.
- 5. The research priorities need to be vetted and the process of analysing the roadmaps needs refinement.
- 6. STAR-IDAZ is useful for seeing who is funding and performing animal health research around the world (bibliometric database). Being part of such a network means having a communication channel direct to other funders and researchers and access to them.
- 7. Collaboration through STAR-IDAZ helps funders get a better return on their research investment. Research funding in animal health is relatively small so working together is important in ensuring investment is directed to the right areas.
- 8. With the IRC roadmaps and networks such as the Global Foot-and-Mouth Disease Research Alliance (GFRA) identifying gaps, STAR-IDAZ can help get them funded.
- 9. Partners must follow their own rules around data sharing but it should be possible to provide details to STAR-IDAZ and making data open and accessible is desirable. It would be good if it was possible to track who was accessing and using the data (traceability).

Research councils and charities

- 1. The roadmaps will be useful to this group, mostly for supporting strategy development, but we need to recognize the limitations: the roadmaps are a component of the work required to develop and justify a strategy, but as donors we still need to engage with committees and consultants to develop a product that will be adopted by our leadership.
- 2. The barriers to adoption of the roadmaps are mostly due to some of the potential limitations and gaps. The following points were the focus of the discussion:



- a. The roadmaps are product focused, and may neglect the broader system. Biosecurity and regulatory systems and frameworks were discussed, and there was a discussion around the opportunity to support research to change regulation and provide evidence to change mandate. The group highlighted the gap around sufficient industry engagement: this is necessary to achieve a practicable product, developing target product profiles, however we all recognized the limitations around IP, or sharing business sensitive data that limits the level and degree of engagement. It was also noted that the regulators should be engaged early on to kill off possible products and technologies that are not going to be taken forward.
- b. How much confidence do we have in the roadmaps, some of the phrases captured included "peer review, quality, validation, confidence, researcher-led agenda". There was also a discussion that researchers may not share unpublished results, up-to-date data may not be captured, and the term "publishing gap" was used.
- c. Some of the topics included in the roadmap are very broad and it was suggested the roadmaps could be more detailed and granular.
- 3. Everyone recognized participation and STAR-IDAZ as a very important advocacy tool. The group then went on to discuss what could help to get more out of their participation. The following points were captured: could be aligned with other research networks, EU Joint Program Initiative was mentioned. There could be more work on access to data, and also on common approaches to data: livestock production data, disease data, and research and development data was discussed. Open access publications were discussed, but the "publishing gap" was mentioned again. More engagement with the private sector would be useful, but the group reiterated the limitations mentioned above.

General Discussion on how the innovation pipeline might be shortened

Addressing the research challenges and barriers to working together

- A. Determining who should fund endemic disease research. It is easier to get a public research grant for work on exotic diseases than endemics.
- B. It is important to define the Target Product Profiles (TPPs) for vaccines, diagnostics and therapeutics.
- C. Standardised Challenge Models would be very useful in, for example, comparing the efficacy of different ASF vaccines. However the different host genetics need to be considered if models are being applied to global issues and challenge models need to replicate the 'field situation'.
- D. Disease control technologies is a competitive area between companies and countries so there are limitations to extent of working together that is possible.
- E. Early engagement with industry is important in ensuring their early work and products are free and suitable for commercial purposes. Researchers first need to ask the



pharmaceutical industry what they need with regard to particular hosts, cell line etc and whether there is a market.

- F. IPR increases the cost of producing vaccines. More organisations involved in the process means more IPR and this increases further across country borders.
- G. Negotiating access to required adjuvants etc can be more costly and trouble than developing or using alternatives.
- H. Laboratory kits used by academia are available for purchase and these can be used to generate data but the data can be owned by the kit producer so the licencing agreement would need to be bought out by the industry partner. Academia therefore need to be open on their methodologies.
- I. As with the kits mentioned above, researchers can make the mistake of using a reagent which is already bound by IP obligations which means they are tied to them.
- J. The problem in animal health is that a lot of the 'easy' research has been done so academia need to add value to the research process. They need to foot some early development costs in terms of technology transfer to attract industry involvement.
- K. Providing industry with first right of refusal is an effective incentive.
- L. It was suggested that GMO will be the new main regulatory issue. GMO vaccines can get licenced but can be difficult and may not be acceptable in some countries/regions.
- M. More investment is needed in basic science and unless this improves then the research pipeline will be stifled. Immunology in particular is underfunded. Pharma companies do still undertake basic science but fewer of them now do it. Should government address this?
- N. Long term issues and diseases such as ASF require investment in basic research e.g. gene function because it hasn't been done before.
- O. A systems (biology) approach is sorely needed as there are currently too many specialists. The universities need (funding) to offer such programmes. It was suggested that more veterinarians should be encouraged to do PhDs.
- P. Continue with the systems approach to animal disease control.
- Q. Hold more workshops such as this bringing together all the different stakeholders and people along the research pipeline including pharma, regulators, diagnostics people.
- R. A database of current research is needed which also shows where current activity sits on the research pipeline. The IRC Roadmap System is aiming to provide exactly this but it is difficult to capture details of progress in current projects. Ideally, the research community would take ownership of their data in the system and ensure their current project information is up to date.
- S. Details of research failures would be useful but it is difficult to capture this and motivate researchers to provide the information – what incentive do they have? Could funders push for them to provide this?
- T. Information management is important. The group was informed of the <u>STAR-IDAZ</u> <u>Data Sharing Statement</u> which is available from www.star-idaz.net).
- U. One Health should be considered as part of the systems approach. The STAR-IDAZ IRC Working Group on Coronaviruses is bridging the gap between the veterinary and human sides by working with ZAPI. It is easier if we focus on those viruses that are currently a problem to both.



- V. Early exposure of young scientists to commercial and regulatory people is invaluable.
- W. Texas A&M's 'Bench to Shop' programme is very useful and more of this should be encouraged. It "enables 21st century researchers (graduate students, post-doctoral fellows, and/or early career faculty) to plan, execute, evaluate, and transition Transboundary Animal Disease (TAD) research technologies to the global marketplace".
- X. There are issues regarding low income settings, deployment of vaccines and market viability. Packaging and distribution of vaccines are considered in the Target Product Profiles (TPP) rather than the roadmaps.



Annex 2: List of Participants

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