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## Comparing US BARDA, EU HERA, and UK ARIA

### Introduction

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In the Queen's Speech 2021, the UK government announced its agenda to create an Advanced Research and Invention Agency ("ARIA"), which will fund high-risk, high-reward research and development. On February 24, 2022, the bill to establish ARIA received Royal Assent and became law.<sup>1</sup> Similarly, the European Commission recently launched the European Health Emergency Preparedness and Response Authority ("HERA").<sup>2</sup> The Biomedical Advanced Research and Development Authority ("BARDA") in the United States serves a similar function to both entities, and may provide a useful framework for ARIA and HERA as they get off their feet. This client alert addresses ARIA's and HERA's proposed role in the development of medicines and analogizes ARIA, HERA, and BARDA.

### UK Advanced Research and Invention Agency ("ARIA")

In creating ARIA, the UK government endeavors to "cement the UK's position as a science superpower."<sup>3</sup> The government plans to invest £14.6 billion in research and development ("R&D") in ARIA's first year, building towards the government's target of spending 2.4% of GDP on R&D across the UK economy by 2027.

ARIA aims to "exclusively focus on projects with potential to produce transformative technological change." The agency will have autonomy over its own research and project choice, and it will recruit researchers from the public and private spheres. ARIA will tolerate a high level of failure in order to encourage investment in high-stakes, high-reward research areas. It will operate across the R&D life cycle. The agency's funding approaches will include inducement prizes, grant/prize hybrids, seed grants, taking equity stakes, attracting private co-financing, and academic and entrepreneurial fellowships.

### EU Health Emergency Preparedness and Response Authority ("HERA")

On September 16, 2021, the European Commission launched HERA, an internal service within the European Commission, aiming to prevent, detect, and rapidly respond to health emergencies. Modeled after BARDA, HERA's main goal is to ensure that medicines, vaccines, and other medical countermeasures are rapidly developed, manufactured, and made readily available for EU citizens. By working closely with EU and national partners, HERA aims to fill a gap in the European Union's health emergency response and preparedness. HERA will focus on assessing threats, supporting research and innovation, addressing market changes, and boosting industrial capacity. Its total budget is €6 billion over the next six years.

The United Kingdom's and European Union's development of ARIA and HERA suggests that these key jurisdictions intend to better prepare for the next public emergency, rather than reacting to issues as they arise, which was often their approach to the coronavirus pandemic.

<sup>1</sup> <https://bills.parliament.uk/bills/2836>.

<sup>2</sup> [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_21\\_4672](https://ec.europa.eu/commission/presscorner/detail/en/ip_21_4672).

<sup>3</sup> <https://www.gov.uk/government/publications/advanced-research-and-invention-agency-aria-statement-of-policy-intent/advanced-research-and-invention-agency-aria-policy-statement>.

## US Biomedical Advanced Research and Development Authority (“BARDA”)

Created in 2006, BARDA is a department of the US government that prepares and maintains an integrated system of medical countermeasures for known, unknown, re-emerging, and novel types of public health emergencies.<sup>4</sup> Some consider BARDA to be the “biomedical DARPA.” DARPA is the Defense Advanced Research Projects Agency, housed within the US Department of Defense; BARDA is a similar agency, but with the directive to procure and develop countermeasures against bioterrorism, pandemics, and emerging diseases. A UK government policy paper published on March 19, 2021 highlights many similarities between DARPA and ARIA.<sup>5</sup> Relatedly, BARDA and ARIA are also analogous in many ways.

BARDA provides an integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies. It does not fund research in basic science. Rather, BARDA focuses on the following program areas: chemical, biological, radiological, and nuclear accidents, incidents and attacks; antimicrobial resistance; pandemic influenza, and emerging infectious diseases. BARDA leverages public-private partnerships to spur innovation, collaborating with private partners to develop promising technologies. In response to COVID-19, BARDA entered into a series of expanded public-private partnerships to develop medical countermeasures and established a single point of entry for product developers to submit their research on such COVID-19 countermeasures.

President Biden has also proposed the creation of a biomedical research agency called Advanced Research Projects Agency for Health (“ARPA-H”) within the National Institutes of Health. Unlike BARDA, which focuses on public health emergencies, ARPA-H would fund research into non-communicable diseases, such as Alzheimer’s, diabetes, and cancer.

### BARDA’s Impact and Lessons Learned

BARDA is the only national agency that actively targets and finances advanced stages of development for medical countermeasures with a high risk profile. The agency’s funding bridges the “valley of death”—the high costs characterizing late stages of product development and clinical trials.<sup>6</sup> The US Congress directed \$6.5 billion in supplemental COVID-19 funding to BARDA for vaccine and countermeasure development through Operation Warp Speed. This funding led to the development of several successful vaccines: Johnson & Johnson, AstraZeneca, Pfizer-BioNTech, and Moderna.

On the other hand, BARDA is not without its critics. BARDA ensures that certain requirements are included as terms and conditions of funding for grants, contracts, and cooperative agreements; some see this as an impediment to progress.

Further fueling its critics, BARDA has also faced longstanding management issues since its creation in 2006. Additionally, a 2018 whistleblower complaint alleged funds earmarked for vaccine development were misappropriated for office furniture removal and administrative expenses.<sup>7</sup> A May 2020 report, issued by the Office of Special Counsel, found that the Department of Health and Human Services had diverted millions of dollars intended for BARDA to other government activities, and failed to inform Congress.<sup>8</sup> As the UK and EU governments move forward with developing

<sup>4</sup> <https://www.medicalcountermeasures.gov/barda>.

<sup>5</sup> <https://www.gov.uk/government/publications/advanced-research-and-invention-agency-aria-statement-of-policy-intent/advanced-research-and-invention-agency-aria-policy-statement>.

<sup>6</sup> <https://www.phe.gov/about/barda/stratplan/Pages/introduction.aspx>.

<sup>7</sup> <https://www.nytimes.com/2021/01/27/us/politics/barda-public-health-watchdog.html>.

<sup>8</sup> <https://osc.gov/Documents/Public%20Files/FY21/DI-16-3098/Subject%20Agency%20Report%3b%20DI-16-3098.pdf>.

ARIA and HERA, they may want to keep in mind both BARDA's successes and failures, and the potential for funds to be misused.

## Conclusion

The fates of ARIA and HERA remain to be seen, but both entities could soon be paving the way for biomedical breakthroughs. If the COVID-19 pandemic is any indication, preparedness for global biomedical threats will remain a key priority shared by the United Kingdom, European Union, United States, and the international community, and there is much to be gained by encouraging innovation in emerging biomedical research areas.