MAIN PRIORITIES	SPECIFIC RECOMMENDATIONS
CHALLENGE 1 – R&D	
Support an integrated, multidisciplinary approach to antigen selection	➤ Research on host-pathogen interactions in vivo ➤ Research for the refining of animal models ➤ Development and exploration of new assays to rapidly screen antibody and T cell functions ➤ Explore emergent in-vitro bioassay technologies and improve in-vitro assay for antibody functional screening ➤ Research for selection and analysis of epitopes ➤ Develop new bioinformatics tools applied to genomics, antigen diversity and antigen expression ➤ Support research on structural vaccinology
Strengthen the science of vaccine adjuvants	➤ Create toolbox of adjuvants with well-defined profile to shape the immune response ➤ Employ systems/omics analysis to improve the discovery of biomarkers predictive of adjuvants' effect ➤ Develop toxicology research on adjuvant-induced inflammation ➤ Combine different adjuvants in prime-boost studies ➤ Cross-species studies of vaccine adjuvants to pinpoint predictability of animal models
Sustain research on vectors and alternative routes of immunisation	➤ Better approach to a combined use of vectors, adjuvants, routes of immunisation ➤ Evidence-based development of heterologous prime-boost strategies to induce long-lasting immunity of alternative routes of immunisation and their testing in pre-clinical and clinical studies ➤ Development of more potent synthetic nucleic acid-based vectors for rapid outbreaks response ➤ Research for the development of novel strategies for mucosal vaccination using purified subunit antigens
Innovative design and harmonisation of clinical trials data and development of analyses frameworks	➤ Enable access to "big data" at the micro and macro level ➤ Build capacities to enable data aggregation across functions, inclusive of data descriptors ➤ Rapidly develop multi-parametric technologies in cell biology ➤ Identify innovative design of clinical trials and methodologies to profile volunteers earlier on in the process
Continue to invest in biomarkers of safety in vaccines, and correlates of protection and of efficacy	➤ Develop expertise and support infrastructures to perform controlled challenges in humans ➤ Set up collaborative cost-sharing programmes in the EU and at international levels (Transatlantic, Asia) to facilitate access to advanced technologies, large populations, rare outcomes, and avoid duplication in investments
CHALLENGE 2: THERAPEUTIC VACCINES	
Establish collaborative cross-expertise network at EU level	➤ Exchange best-practice, including successful and unsuccessful approaches, share know-how and technology ➤ Design and perform multi-centre clinical studies
Foster early dialogue with regulatory bodies	➤ Facilitate early interactions and regular dialogue with regulators, e.g. through EC led workshops ➤ Regulators to assess the feasibility of developing EU-level guidance for therapeutic vaccines, including in specific disease areas
Develop targeted funding opportunities	➤ Bridge the gap between research and market and create efficient financial markets ➤ Government policies to improve equity financing ➤ Lower financial risk perception through appropriate mechanisms, including interactions with payers
CHALLENGE 3: INNOVATIVE PROCESSES FOR VACCINE MANUFACTURING AND QUALITY CONTROL	
Translate innovations into technologies	➤ Promote closer collaboration among scientists, engineers and regulators ➤ Offer continuity of funding beyond concept demonstration ➤ Set up a task force of regulators and policy-makers to support plans based on scenario planning
Develop flexible manufacturing systems	➤ Investigate how to decentralise manufacturing capacity through a more localised supply base ➤ Support the adoption of single use systems and technologies to minimise variations between sites
Bridge technology and science: collaboration between engineers and biologists	➤ Investing in thermostability enabling technologies ➤ Test alternative delivery devices: increasing vaccine stability and new fill-in ➤ Investment in formulation expertise in the research process ➤ Develop and validate improved potency assays to increase relevance while simplifying testing ➤ Develop assay platforms allowing for rapid characterization for different manufacturing systems ➤ Develop robust assays for in-process control for both up-stream and down-stream processing
Improve manufacturing operations and identify new purification techniques	➤ Improved chromatographic techniques adapted to adenoviruses or particle-based vaccines

CHALLENGE 4: RESEARCH INFRASTRUCTURES

Reinforce vaccine Research Infrastructures	➤ Develop the network of existing EU facilities and cross border connection to rapidly set-up trials and recruit subjects ➤ Upgrade or create new infrastructures in the areas where gaps exist or capacity is insufficient ➤ Promote harmonisation/standardisation among facilities in five key areas: genomics and bioinformatics facilities; repository and collections ; high throughput protein production and crystallography facilities; animal facilities; immunisation technologies ➤ Develop and promote access to innovative technology platforms: live vectors, adjuvant, formulation ➤ Consolidate and provide access to repository and collections: biobanks and well-characterised pathogen strains
Provide support to clinical research infrastructure	➤ Map centres with methodological competences and map volunteers/specific populations ➤ Identify or develop cohorts (registries) ➤ Enable human challenge models ➤ Further develop and structure clinical trial centers coupled with immunomonitoring, imaging, laboratory testing and functional monitoring of physiological parameters
Improve GMP manufacturing capabilities	➤ Secure clear guidance on GMP level for manufacturing and quality control ➤ Establish funding schemes to fund the GMP manufacturing of vaccines for testing up to phase 2 ➤ Facilitate the access to infrastructure required for GMP manufacturing ➤ Establish a central European platform to measure the purity of GMP vaccine batch

CHALLENGE 5: VACCINE SMEs

Establish a network of vaccine SMEs involved in human vaccine R&D at EU-level	➤ Create forums and a European network to push innovation, share knowledge and experience, as well as to conduct a comprehensive needs assessment ➤ Create a vaccine innovation community portal to improve the exchange information, opportunities, services and infrastructures at EU level
Ease SMEs access to scientific and technical resources and skills at the most critical phases	➤ Facilitate SMEs' access to new technologies to reduce R&I costs and timing ➤ Effective matchmaking and interaction between SMEs and large companies
Support better SMEs early access to regulatory expertise	➤ Facilitate the establishment of early stage contacts with regulatory bodies ➤ Enhance the visibility of services that regulatory bodies can provide at national and EU level
Foster competitive collaborative projects between SMEs and larger companies	➤ Develop an advising mechanism to provide SMEs with easier access to existing facilities and platforms ➤ Organise commercial contact-making workshops ➤ Set-up new instruments allowing SMEs to share R&D projects on the 'Bio-Europe' partnering model ➤ Establish an EC "window" awards to successful large pharma-SMEs R&I collaborations
Sharpen financial instruments and attracting risk capital towards SMEs	➤ Invest in improving the public perception of vaccines as a strategic public health tool ➤ Better adapt current instruments to vaccines SMEs needs

CHALLENGE 6: TRAINING

Identify and profile target groups for training	➤ Adapt the training offering in terms of content and format to specific groups ➤ Map out and describe competency profiles for different vaccinology related functions
Review and adapt training formats, accessibility and recognition	➤ Collaborate with higher education organisations and companies to incentivise training in vaccinology and increase accreditation ➤ Set-up specialised initial and life-long training including courses covering the entire process from vaccine R&D to licensure
Invest in training the trainers	➤ Establish vaccine training platforms to allow the sharing and shipment of equipment required for training ➤ Fund the establishment of facilities devoted to training for GMP manufacturing and train the trainers

CHALLENGE 7: COMMUNICATION ON IMMUNISATION AND THE HESITANCY CHALLENGE

Implement stratified monitoring of acceptance attitudes and sentiments towards vaccination	➤ Establish a tool capable of monitoring acceptance attitudes, risk awareness, sentiments towards vaccines and vaccination programmes at EU level ➤ Develop metrics of vaccination acceptance ➤ Design and pilot interventions
Establish multi-disciplinary networks of expertise and an EU level center of excellence	➤ Support regional and national immunisation advisory groups with regards to vaccine hesitancy ➤ EU institutions to facilitate the formation of a European community of practice on vaccination uptake ➤ Bring together experts from social and behavioural science, neuroscience, social marketing, communication and health education
Make healthcare professionals and public health stakeholders effective advocates of vaccination	➤ Implement innovative shifts in the curricula offerings for healthcare workers to equip them with the right skills and confidence to appropriately assess vaccination needs and effectively communicate on vaccination ➤ Fund vocational and on-the-job communication training programmes for public health staff and immunisation programme managers ➤ Educate future generation about infectious disease, immunology and public health, e.g. through school-based educational programmes, with a view to institutionalising the role of vaccination as a cornerstone of public health
Engage with civil society organisations	➤ Provide appropriate funding and build partnerships to collaborate with such organisations to help building awareness, disseminating and creating knowledge on vaccination needs