Deliverable 5.5

Outcomes of stakeholder workshops exploring TNA to genome editing technologies

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Changes with respect to the DoA (Description of Action)

This first version of the deliverable is in line with the DoA. This deliverable will be updated accordingly as more think tanks will be organised.

Table of Content

1. Summary of results

The EuroFAANG Research Infrastructure project funded by the EU Horizon Europe program has made significant strides in establishing a framework for responsible genome editing research and application in farmed animals. Through a collaborative and strategic approach, experts in genome editing, ethics, and animal breeding across Europe have created a platform for informed dialogue for Deliverable 5.5.

Our think-tank event on gene editing in farmed animals, organised as part of this project, has delivered valuable insights. It revealed a complex setting characterised by both substantial opportunities and significant barriers. Gene editing can potentially revolutionise the agricultural sector, improving animal health, welfare, and sustainability. However, it faces hurdles related to limited genome function understanding, phenotypic uncertainty, societal perceptions, regulatory divergence, market acceptance, off-target effects, resource and testing gaps, legislative ambiguity, definitions, historical trust issues, and genetic diversity concerns.

We've identified key priority areas, including consumer and stakeholder engagement, educational outreach, genomic variant testing, health traits development, animal welfare improvement, and scalability enhancement. Focusing on these areas will be vital in realising the potential of gene editing.

The next steps involve creating a volunteer subgroup to refine terminology related to genome editing in farmed animals. While our think-tank was engaging, it has become evident that more extensive discussions are needed. The positive feedback we've received underscores the importance of such initiatives. We plan to use the insights gathered to organise the next think-tank in Spring 2024, and a questionnaire will be sent to participants to gather feedback and enhance its effectiveness. Our ultimate goal is to drive responsible gene editing practices, benefiting the sector and society alike.

2. Introduction

The EU Horizon Europe research program funds the EuroFAANG Research Infrastructure (RI) project under *HORIZON-INFRA-2022-DEV-01.* This call focuses on developing, consolidating and optimising the European research infrastructure landscape and maintaining global leadership, ultimately creating a world-leading, coherent, agile and attractive RI landscape in Europe. This project will look at how to develop the concept for implementing Euro-FAANG RI. RIs are facilities, resources and services used by the research communities to conduct research and foster innovation in their fields. They include major scientific equipment (or sets of instruments), knowledge-based resources such as collections, archives and scientific data, e-infrastructures, such as data and computing systems and communication networks and any other tools essential to achieve excellence in research and innovation.

The EuroFAANG RI aims to streamline interdisciplinary capabilities for Genotype-to-Phenotype research in terrestrial and aquatic farmed animals and provide transnational access to all the relevant facilities, expertise and knowledge to European stakeholders. This will address the need to bring together national facilities at the pan-European level in animal genetic resources, phenotyping and breeding, and animal health, which was identified as a gap in the infrastructure landscape by the 2021 ESFRI Roadmap. The proposal builds on the foundation of the six H2020 EuroFAANG projects, AQUA-FAANG, BovReg, GENE-SWitCH, GEroNIMO, HoloRuminant and RUMIGEN. It connects with existing infrastructures for data management and animal agriculture in the European research infrastructure landscape.

Within this framework, work package (WP) 5 aims to develop a framework for sharing and expanding capabilities in genome editing as a route to applying FAANG[1] data for understanding the genotype-to-phenotype link in farmed animals. To achieve this, three main objectives or tasks are:

I. Provide a route to apply FAANG data in vitro by creating a framework for access to high-throughput phenotyping (HTP) platforms to validate candidate causal variants.
II. Devise a framework to facilitate access to genome editing technology in vivo in i) animal facilities equipped to handle/raise and conserve genome-edited animal lines across generations and ii) in silico modelling studies to predict the effect of introducing an edit into a breeding population.
III. Creating a European think-tank on genome editing in farm animals, connecting national ethics committees, projects and research infrastructures.

Deliverable D5.5, a crucial part of Work Package 5 (WP 5), is closely aligned with WP 5's core mission of establishing a framework for leveraging genome editing technology to advance our understanding of the genotype-to-phenotype relationship in farmed animals. This deliverable focuses on the third objective and represents the results of stakeholder workshops centred on exploring Transnational Access (TNA) to genome editing technologies. These workshops, organised by EFFAB, facilitate in-depth discussions regarding genome editing's utilisation, barriers to its implementation, and the role of TNA in providing access to essential capabilities and facilities. The outcomes of these workshops contribute to the mission of the European think-tank on genome editing in farm animals, shaping responsible genome editing practices while emphasising animal health and welfare and guiding societal and scientific opinions and policies.

3. Core Report

3.1. Methodology

The think-tank aims to connect experts in genome editing, ethics, and animal breeding across Europe to create a platform for responsible genome editing research and application in farm animals. This platform is a hub for discussions and collaboration on critical topics, such as ethics, barriers to adoption, societal perspectives, defining terms, and maintaining scientific rigour in genome editing. It aims to foster dialogue, facilitate sharing of insights and practical applications, and to address potential challenges related to genome editing in farm animals.

The methodology for building up our European think tank on genome editing in farm animals was a strategic and collaborative process. We initiated our efforts by establishing a network of experts in Europe in genome editing, ethics, and animal breeding. The initial invitation email served as a crucial first step in connecting with these experts and forming the foundation of our think tank. In this email, we requested interested participants to confirm their availability through a poll. This step allowed us to gauge interest and availability, ensuring we could build a group of dedicated individuals.

Out of the 100 individuals we initially contacted, we received enthusiastic responses from 63, all of whom expressed their willingness to participate in the think tank. Among the available dates, the 5th of October emerged as the most suitable, with 52 attendees confirming their presence, and all signed a Non-Disclosure Agreement (NDA). This high response rate underscored the enthusiasm and commitment of our target audience, which included a well-balanced mix of expertise in the relevant fields.

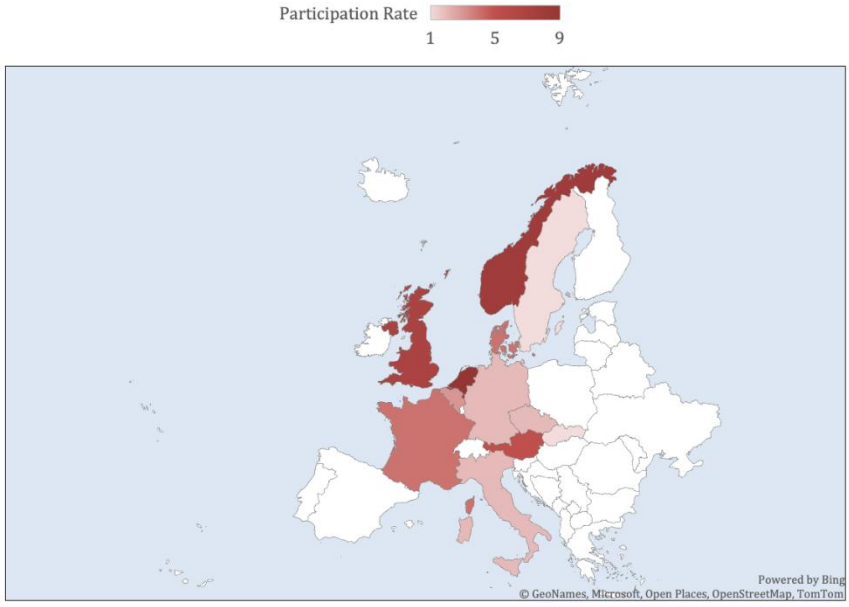

Figure 1 shows the countries that were represented in the think-tank. The formation of the think-tank focused specifically on European stakeholders, with a small number of key stakeholders from Canada, the US and Kenya with links to Europe also invited.

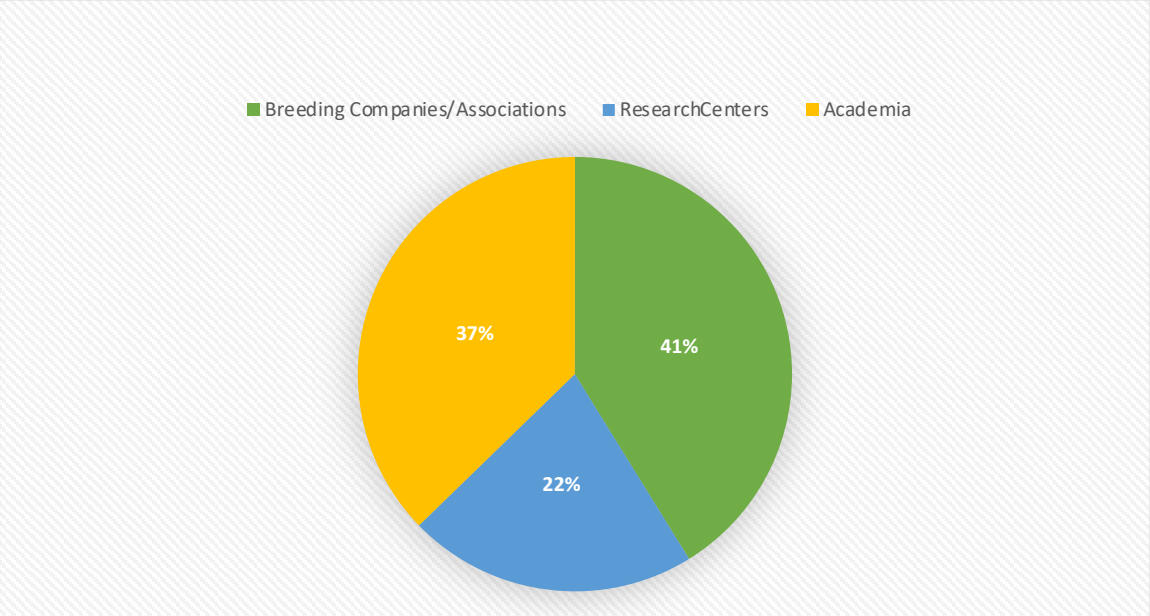

Figure 2 shows the sectors represented during the think-tank (52 participants including the 5 facilitators), showing an even spread across breeding companies, universities and research centres that are specialised in advancing knowledge and innovation in Animal Breeding and Genetics.

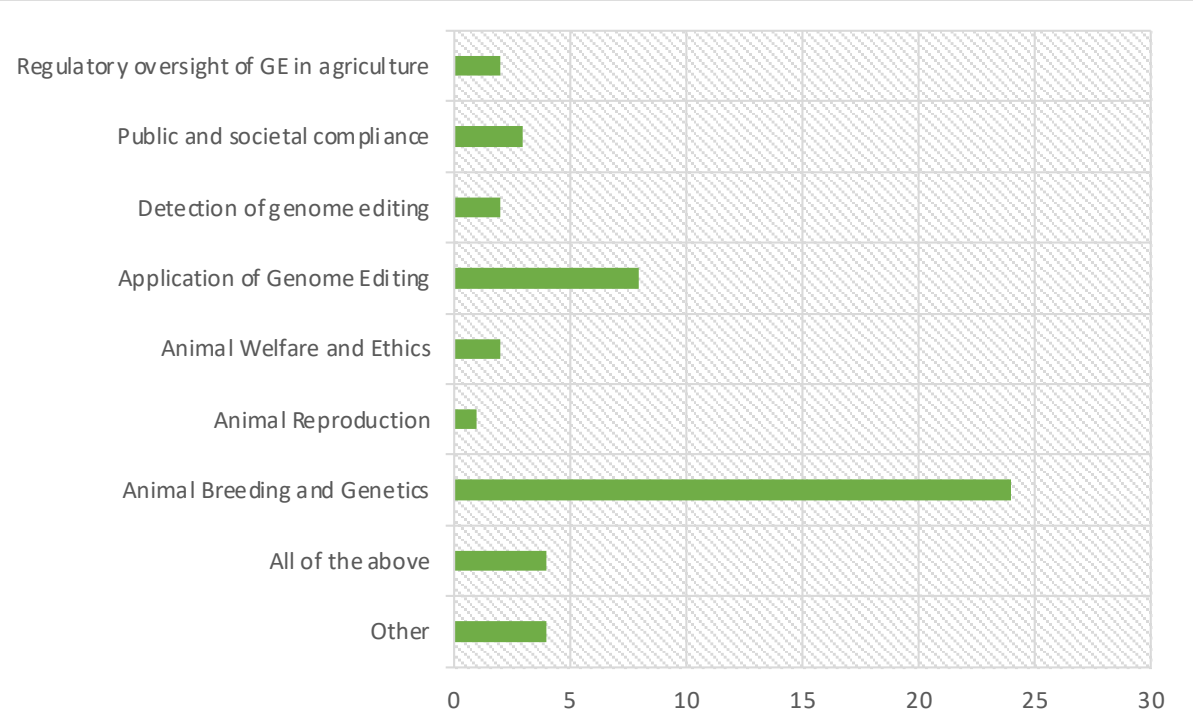

Figure 3 shows the expertise of the participants of the think-tank (52 participants including the 5 facilitators). Each discipline had at least one representative and expertise spanned ethics, policy, animal breeding, industry and research and academia as we had planned.

Once we had a significant number of confirmed participants, we proceeded with the following methodology:

- Introduction and Orientation: We began the think tank by introducing key organisations and the Euro-FAANG project, setting the stage for the following discussions. The following slides were used to introduce and summarise the main role of the think-tank and the expected outcome for participants:

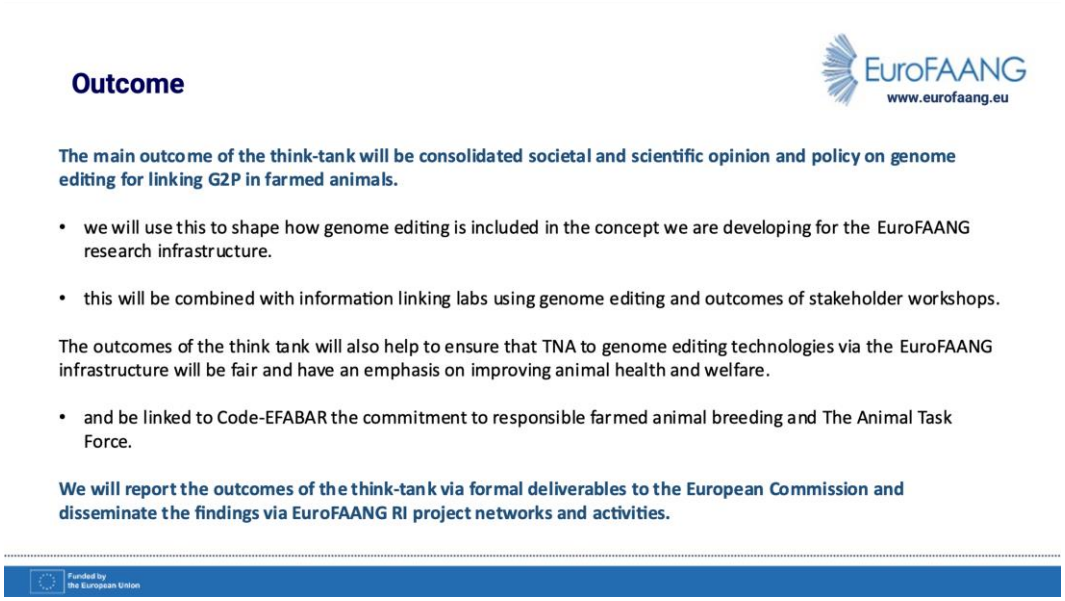

Figure 4: Introductory slides describing the role of the think-tank and main outcomes for the participants.

- Breakout Sessions: Participants were divided into smaller groups, focusing on priorities, opportunities, and barriers to genome editing in farmed animals. Using online whiteboards **(see Annex 6.1)** and sticky notes allowed for the collaborative sharing of insights and ideas. These sessions enabled in-depth discussions and critical examination of various topic aspects. The following slide was used as a primer for these discussions:
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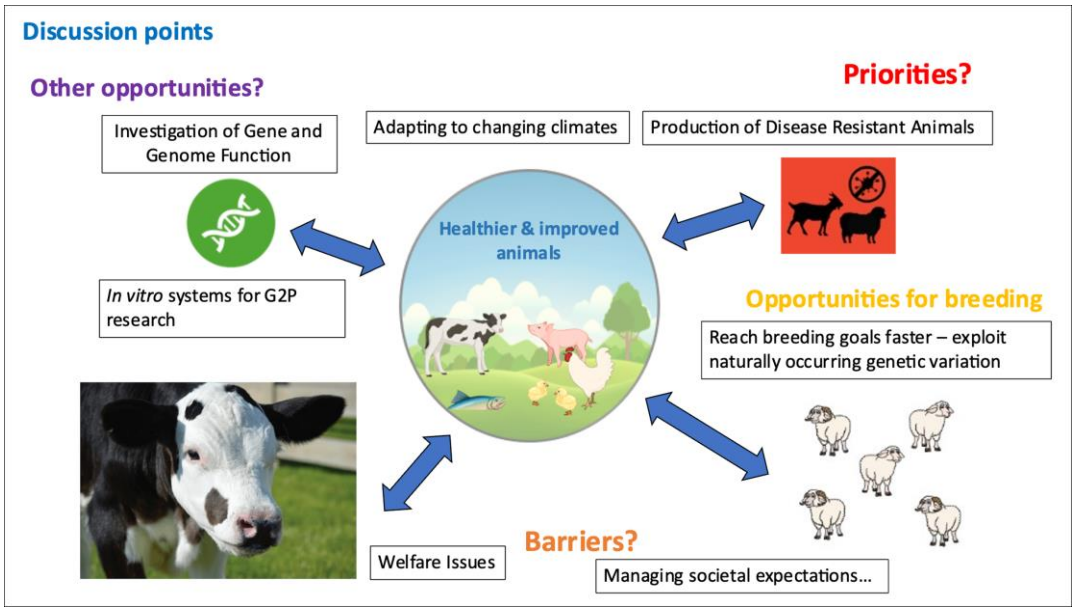

Figure 5: Primer slide for the think-tank discussions.

- Rapporteur Designation: Each group selected a Rapporteur to summarise and present the key points discussed during the breakout sessions. This ensured that valuable insights were captured and communicated effectively.
- Presentation of Group Findings: In the final segment of the think tank, each Rapporteur had a 3-minute window to present the key findings from their respective breakout sessions. This step provided an overview of the different groups' priorities, opportunities, and barriers.

This methodological approach facilitated meaningful discussions, knowledge exchange, and the collective identification of critical issues and opportunities related to genome editing in farm animals. The outcome was a comprehensive understanding of the subject, which will guide our future efforts to create a platform for responsible genome editing research and application in this domain.

3.2. Results

Gene editing in farmed animals can revolutionise agriculture, enhancing animal welfare, disease resistance, and productivity. However, it has its challenges. The think-tank discussions emphasised the importance of effectively addressing various barriers, seizing opportunities, and setting clear priorities to navigate the complex landscape of gene editing in farmed animals. The detailed discussion from the four breakout sessions can be found in **Annex 6.2**, but the following summarises the discussion by participants:

I. Barriers to Gene Editing in Farmed Animals: Challenges and Hurdles

Gene editing in farm animals offers tremendous potential but faces significant obstacles. This section explores the key barriers and challenges that must be addressed for successful implementation.

- **Limited Genome Function Understanding:** A common challenge was a need for more knowledge about genome function, resulting in few known gene editing targets.
- **Phenotypic Uncertainty:** The difficulty in predicting and validating expected phenotypes for gene-edited animals was another common challenge highlighted by participants.
- **Societal Perception and Regulatory Divergence:** Disparate societal perceptions and differing regulatory approaches between regions and countries were recognised as significant barriers to gene editing adoption.
- **Market Acceptance:** Market acceptance along the entire value chain, not just among producers, poses potential challenges.
- **Off-Target Effects:** Participants expressed concerns about the potential off-target effects of gene editing, emphasising the need for more research in this area.
- **Resource and Testing Gaps:** There is a need for improving resources and testing to validate genomic variants and enhance the efficiency of gene editing techniques.
- **Legislative Ambiguity:** The unclear and evolving legislation and regulations surrounding gene editing were identified as an additional barrier to adoption.
- **Definitions:** Refining proper definitions for key terms like “Genome Editing”, “GMOs” and “Animal Welfare”.
- **Historical Trust Issues:** A lack of trust in animal farming and its impacts on the environment, animal welfare, and human health emerged as a barrier to acceptance.
- **Genetic Diversity Concerns:** Technical challenges associated with spreading beneficial edits widely in populations while maintaining genetic diversity were identified as a significant challenge.
- **Traceability Issues:** Distinguishing edited animals from their descendants and addressing traceability concerns was highlighted as a critical factor to consider.

II. Opportunities in Gene Editing for Farmed Animals: Unlocking Potential

Gene editing presents various opportunities to revolutionise agriculture. Here, we highlight the potential benefits and advancements of gene editing in farm animals.

- **Enhanced Animal Health and Welfare**: Gene editing offers the opportunity to improve animal health and welfare by conferring resistance to diseases such as e.g. avian influenza, African swine fever, and infectious bursal disease.
- **Improved Breeding Progress:** Faster breeding progress and the integration of traits without traditional breeding burden were seen as significant opportunities.
- **Societal Benefits Showcasing:** The think-tank discussions highlighted the potential for showcasing societal benefits in areas like climate adaptation and the green transition.
- **Biomedical Research Advancement:** Gene editing in animals can advance biomedical research, potentially leading to breakthroughs in human health.
- **Genomic Variant Testing:** High-throughput CRISPR screens for testing of genomic variants to better understand their effects, and becoming available for farmed animals, and have the potential to yield valuable opportunities.
- **Cell and Tissue Culture Systems:** the development of more physiologically relevant cell and tissue culture systems for farmed animals to safely test gene edits in vitro before whole animal applications in vivo emerged as an opportunity.
- **Genome Characterisation:** Participants emphasised the opportunity of characterising animal genomes better to identify variants that could address future challenges, such as those related to climate change impacts.
- **Sustainable agrifood systems**: Healthier and well-adapted animals as sources of high nutritional food and high-value biomass are a foundation of food safety and, therefore, public health

III. Priorities for Advancing Gene Editing in Farmed Animals: Focus Areas

To effectively utilise gene editing in farm animals, we outline key priority areas that demand attention and action to ensure responsible and productive implementation.

- **Consumer and Stakeholder Engagement:** Conducting consumer and stakeholder engagement to understand concerns, build trust, and communicate guarantees around oversight and traceability was considered a priority.
- **Educational Outreach:** Prioritising education not only for consumers but also for the entire food supply chain, including farmers, processors, retailers, and public authorities, was identified as crucial.
- **Genomic Variant Testing:** Testing genomic variants to understand their effects was recognised as a priority to enhance the effectiveness of gene editing in farmed animals.
- **Health Traits Development:** Addressing animal and human health traits, such as disease resistance and xenotransplantation, was considered a priority in gene editing applications.
- **Animal Welfare Improvement:** Enhancing animal welfare through gene editing emerged as a priority to align with societal values and sustainability goals. Participants recognised the opportunity to prioritise disease resistance, particularly for avian influenza, African swine fever, and other notifiable diseases.
- **Scalability Enhancement:** Improving the scalability of gene editing techniques, through training and capacity building in the required technical expertise, for efficiently editing more significant numbers of animals 'on-farm' was emphasised as an important opportunity.
- **Cell and Tissue Culture Systems:** the development of physiologically relevant cell and tissue culture systems to safely test gene edits in vitro before whole animal applications emerged as an important area to prioritised minimising use of animals and providing tools for high-throughput CRISPR screens.

4. Conclusion and Next Steps

The discussions in the four break-out rooms during the think-tank event on gene editing in farm animals revealed a complex setting. While gene editing offers substantial opportunities for the sector, it also faces tough barriers.

Addressing these challenges and prioritizing key areas will be crucial to harness the potential of gene editing in farm animals. Clear communication of research and stakeholder engagement, including consumers and the broader supply chain, will ensure that these challenges are properly addressed.

As the agricultural landscape evolves, gene editing stands as a tool that can help address pressing issues like disease resistance, animal welfare, and sustainability. The insights shared during this event contribute to a better understanding of how gene editing can shape the future of farming.

Next Steps

Following the conclusion of the think-tank, it was unanimously agreed that the most effective path forward is establishing a dedicated volunteer subgroup drawn from the core team. This subgroup will be pivotal in accurately defining the terminology associated with genome editing in farmed animals. The collective sentiment among participants was that while the think-tank was engrossing, it demanded a more extensive dialogue.

The positive feedback we've received following these discussions underscores the significance of initiatives like this. The established network of participants in the think tank is leveraged to further refine and specify the mapping and information collection on the use of gene editing in farmed animals, both in vivo and in vitro (D5.2). This will provide a clear depiction of the barriers and threats, as well as the potentials and opportunities, enabling the prioritization of measures for the promotion and implementation of gene editing in farmed animals. The subsequent step is to harness the insights gathered from the think-tank and the requirements for the Research Infrastructure to plan the next edition in Spring 2024.

To ensure that our next event continues to succeed, we will be disseminating a questionnaire to all participants to gather valuable feedback and suggestions on enhancing the think-tank's effectiveness.

5. Annexes

5.1. Whiteboard used for the Think-Tank.

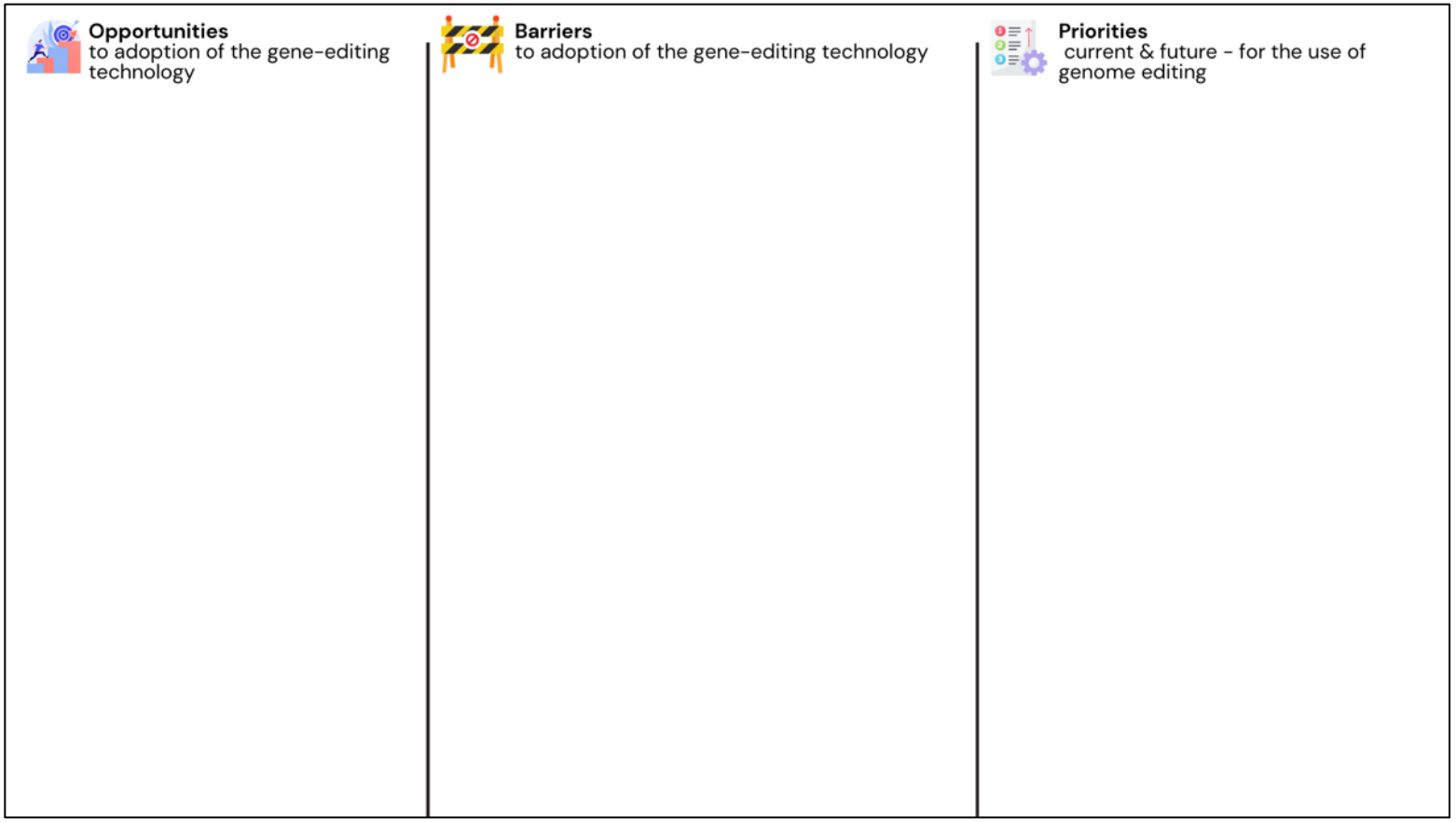

Figure 4 The whiteboard used during the breakout sessions.

5.2. Results of Discussions for the four different groups during the Think-Tank.

Each group was assigned a facilitator to ensure the smooth running of each breakout room.

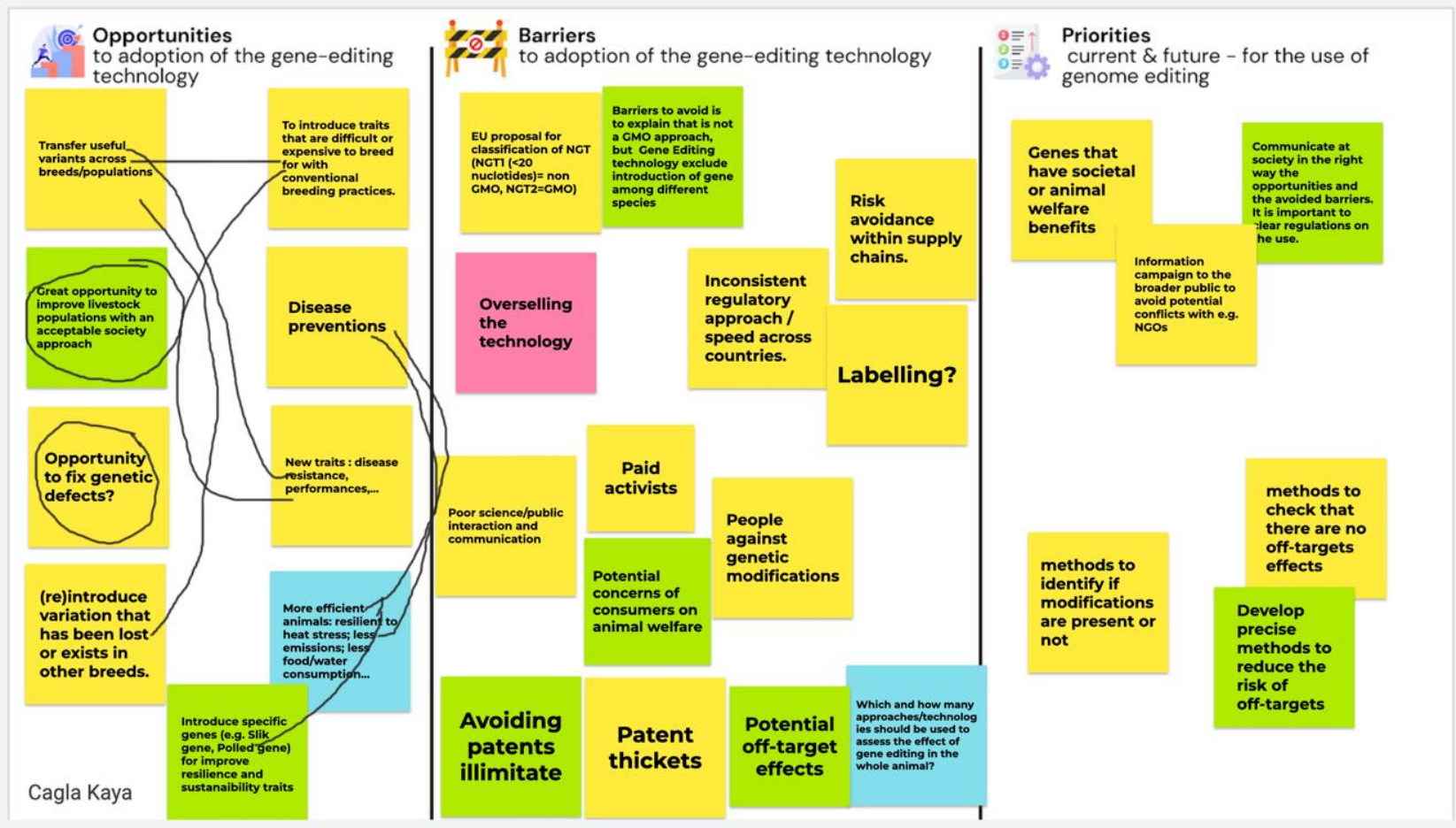

Figure 5 Group 1, which Çağla Kaya (EFFAB) facilitated.

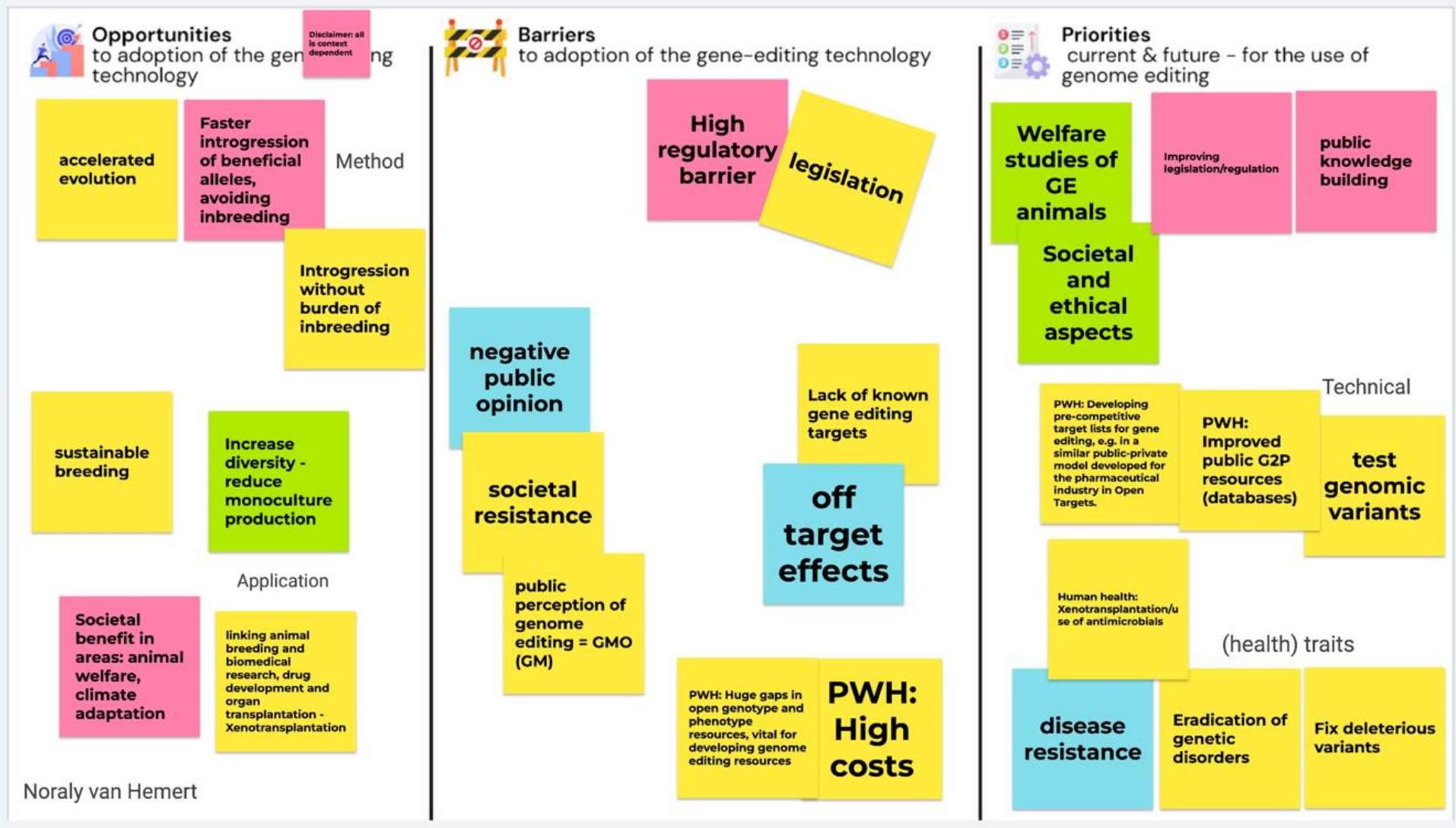

Figure 6 Group 2, which Noraly Van Hemert(EFFAB) facilitated.

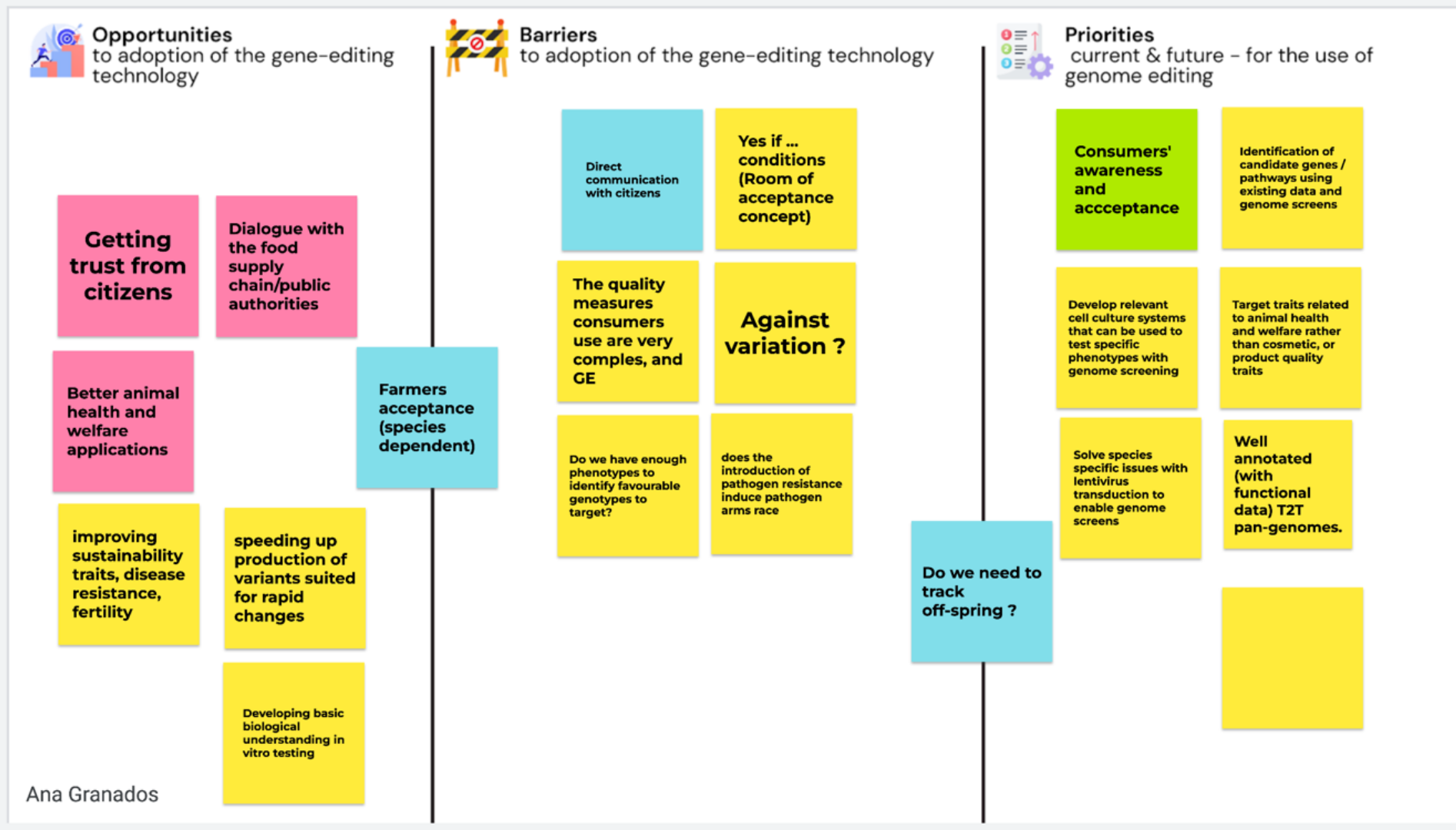

Figure 7 Group 3, which Ana Granados Chapette facilitated(EFFAB).

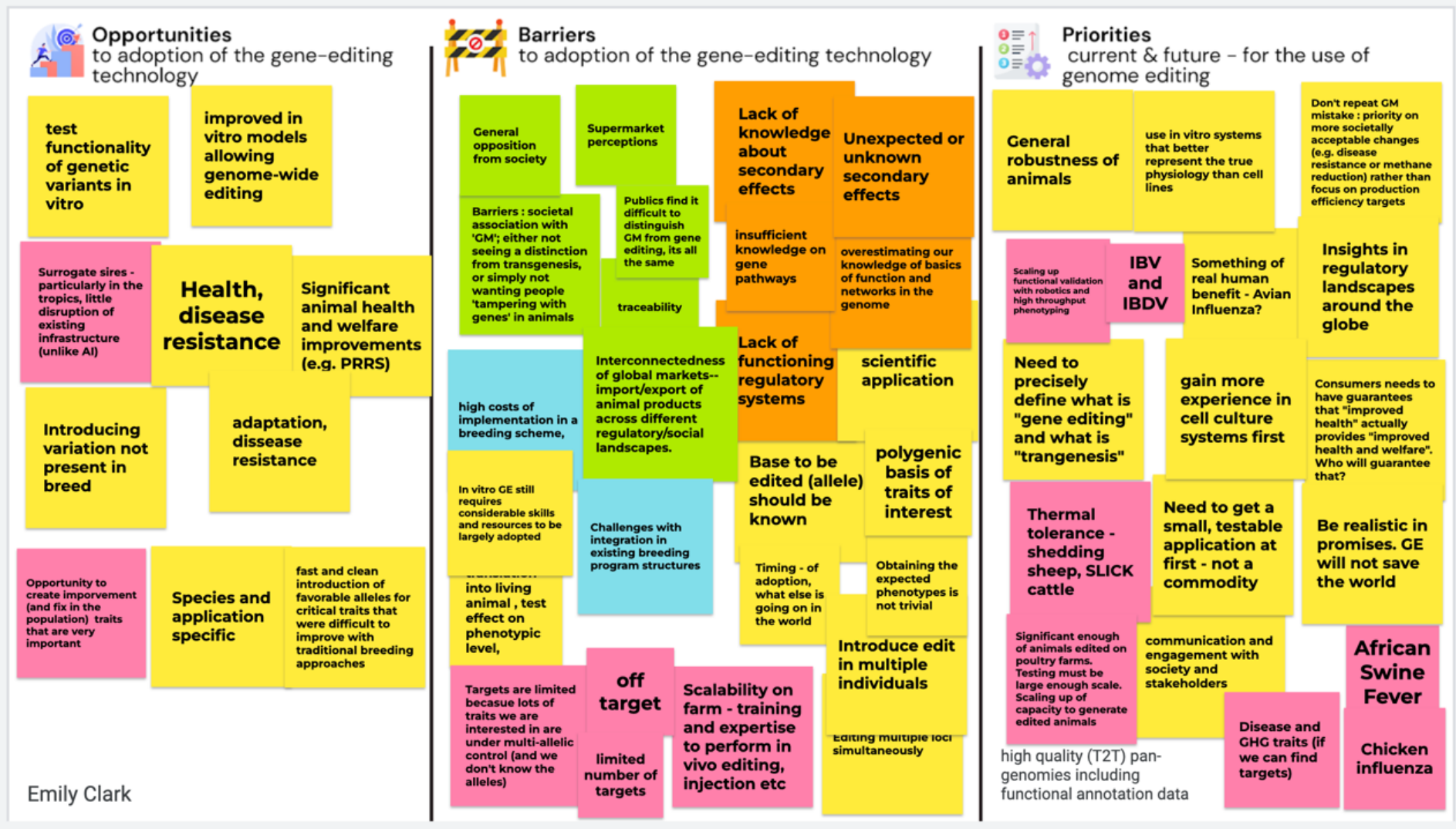

Figure 8 Group 4, which Emily Clark (UEDIN) facilitated.