5th International Conference on Malaria Vaccines for the World (MVW) 2019

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Day 1: 8th May 2019

Simon Draper (University of Oxford) kicked-off the conference and introduced the content of day 1, focused mostly on pre-erythrocytic *Plasmodium falciparum* sporozoite PfSPZ-based vaccines and blood-stage vaccines.

SESSION 1: OPENING PLENARY SESSION

Adrian V.S. Hill (University of Oxford) gave an overview of the development of multi-stage malaria vaccines at the University of Oxford. Despite the challenges for a malaria vaccine to be effective, requiring induction of an exceptional immunogenicity with extremely high antibody levels and T cells frequencies, recent advances point to the feasibility of achieving a subunit vaccine for malaria endemic countries. He summarized the latest advances on safety, immunogenicity and efficacy of the R21/Matrix-M vaccine designed to induce high antibody titers, the prime-target strategy with viral vectors to induce liver resident memory T cells, and briefly on transmission blocking sexual stage vaccines.

Stephen L. Hoffman (Sanaria) gave an overview of Sanaria’s malaria vaccine development plans, including target populations in Africa and travellers from high-income countries. Hurdles faced include the complexity of the human immune response and dysregulation due to previous exposure, and different responsiveness depending on age or genetic background, as well as the complexity of the parasite, in terms of variation of target epitopes and transmission intensity. He also presented the goals and timelines for the licensing of the PfSPZ vaccine, and the studies to halt the transmission and eliminate malaria in Bioko Island, Equatorial Guinea.

SESSION 2: PFSPZ-BASED VACCINES: PHASE 3 TO LICENSURE TO DEPLOYMENT TO USE IN ELIMINATION CAMPAIGNS TO NEXT GENERATIONS

Stephen L. Hoffman (Sanaria) presented plans for finalizing the immunization regimen for the PfSPZ vaccine Phase 3 clinical trials in non-immune populations. He covered how the schedule was optimized regarding dose and intervals, as well as the verification of the optimal regimen against homologous and heterologous Controlled Human Malaria Infections (CHMI). He presented the 3-dose regime, which has shown a high efficacy in two subsequent CHMI and heterologous CHMI. Next, Said Jongo (Ifakara Health Institute and Bioko Island Malaria Elimination Program) presented the plans for finalizing the immunization regimen for the PfSPZ vaccine for Phase 3 clinical trials in semi-immune adults in Africa. He concluded that 3 doses given on days 1, 8, and 29 were as good if not better than a 5-dose regimen observed in previous studies.

Thomas L. Richie (Sanaria) presented the current status and mid term plans for the PfSPZ vaccine. The immediate goal is to obtain the marketing authorization. He reviewed safety data of 4,902 doses of PfSPZ in 1,526 volunteers (5 months to 65 years in age) showing the vaccine to be safe and well tolerated. Future studies include evaluating the value of boosting, the feasibility of a vaccine for pregnant women, and cross species protection. Peter Billingsley (Sanaria) (on behalf of Salim Abdulla, Ifakara Health Institute and Bioko Island Malaria Elimination Program) covered the Equatorial Guinea Malaria Vaccine Initiative testing the PfSPZ vaccine in Bioko Island. Cluster randomized trials will be performed to test mass vaccine effect, as well as a “stepped wedge” approach to optimize standard malaria control efforts coupled with full vaccine coverage for an effective elimination program. Patrick
Duffy (Laboratory of Malaria Immunology and Vaccinology, NIAID, NIH) (on behalf of Agnes Mwakingwe, Laboratory of Malaria Immunology and Vaccinology, NIAID, NIH) presented data on PfSPZ-CVac trials using chloroquine and, for the first time, pyrimethamine. A high dose regime with pyrimethamine was safe, well-tolerated, prevented blood stage parasitemia and may induce heterologous sterile protection.

Shahid Khan and Meta Roestenberg (Leiden University Medical Center) presented the results of the first efficacy trial of an early arresting genetically attenuated PfSPZ vaccine with two knock-out genes, PfSPZ-GA1, administered by needle and syringe in malaria naïve adults challenged with mosquito bites. Overall, PfSPZ-GA1 was safe and well tolerated but sterile protection was achieved in only 3/26 volunteers, with a delayed parasitemia up to day 12. PfSPZ-GA1 and PfSPZ vaccines exhibited similar immunogenicity in terms of antibody and cellular responses. Next, Ashley Vaughan (Seattle Children’s Hospital Research Foundation) presented the results of the efficacy trial of another Genetically Attenuated Parasite (GAP) vaccine with three knock-out genes, PfSPZ-GAP3KO. Half of the volunteers immunized with two different regimens became infected, with no delay in prepatency.

SESSION 3: PFSPZ-BASED VACCINES: INNOVATIONS AND IMMUNOLOGY TO IMPROVE EFFICACY AND REDUCE COST OF GOODS

Abraham Eappen (Sanaria) presented the successful in vitro production of PfSPZ (iPfSPZ), showing that cultured iPfSPZ are fully infectious, develop similar oocysts as those produced in vivo (in the mosquito), and the yield is three-fold greater. This technology will help achieve an efficient, scalable and automatable system that will reduce the cost of goods for vaccine development. B. Kim Lee Sim (Sanaria) presented work done at Sanaria to take into account the genetic diversity and breadth of protective immunity using hybrid strains and mixed strains of PfSPZ. The goal is to seek genetic diversity using different strains and keep selected phenotypic characteristics of NF54.

Shahid Khan and Chris Janse (Leiden University Medical Center) then presented efforts to develop the next generation of late liver stage arresting GAP vaccines in mice. Transgenic Plasmodium berghei parasites expressing Plasmodium falciparum PF48/45 can be used to assess the transmission blocking potential of the vaccine candidate. Rodent parasites can express P. falciparum antigens in their native form. They can be used as effective expression systems, as well as means to rapidly characterize P. falciparum vaccine candidates. Next, Stefan Kappe (Seattle Children’s Hospital Research Foundation) presented work on the generation of genetically-engineered replication-competent whole P. falciparum parasite vaccines. Comparing replication-competent (LARC GAP) with replication-deficient (EARD GAP) vaccines, better responses and protection are obtained when the parasite develops further and the host immune system is exposed to a larger and more diverse biomass of antigens.

Stephen L. Hoffman (Sanaria) (on behalf of Sumana Chakravarty, Sanaria) presented Sanaria’s strategies for improving immunogenicity of PfSPZ vaccines by the use of adjuvants, showing increased levels of protection in mice. Next, Claudia Daubenberger (Swiss TPH) presented lessons learned from immunological studies in PfSPZ vaccine trials in malaria pre-exposed people. IgM antibodies were induced that targeted the circumsporozoite protein (CSP) and inhibit sporozoite invasion and growth in hepatocytes. Unconventional T-cell subsets analyzed by high-dimensional flow cytometry showed an expansion and phenotypic change upon blood stage parasitemia. Vy61 T cells appear to be involved in malaria immunity in a way that acts in an adaptive-like, long-term alteration of the immune response after encountering blood stage infections.
Finally, **Stephen L. Hoffman**, presented strategies to complement vaccine protection with human monoclonal antibodies (mAbs). Several population groups such as the elderly, infants, HIV-positive individuals, vaccine non-responders, travelers and military personnel could benefit from the immediate protection afforded by injection of protective mAbs. Sanaria performed comparative analysis with the mouse mAb 2A10 by immunofluorescence assays (IFA) and Inhibition of Sporozoite Invasion (ISI) assays and ELISA with the anti-PfCSP human mAb as reference standard. Next steps include further functional assays to finalize the prioritization and selection of the best mAb(s) for further development.

**SESSION 4: RECENT ADVANCES – BLOOD-STAGE VACCINES**

**Sarah Silk** (University of Oxford) presented the safety, immunogenicity and efficacy of vaccine candidates based on PfRH5, a leading blood stage target, tested in Phase I/IIa clinical trials. RH5.1/AS01B induced higher antibody response than VV-RH5. RH5.1/AS01B was safe and well-tolerated, with no differences in antibody magnitude between doses. A 10μg dose following the 0-1-2 month regimen showed a modest but significant impact on parasite multiplication rate (PMR) following CHMI and reboosting, and re-challenging 4 months later resulted in higher antibody responses and impact on PMR. Next, **Carolyn Nielsen** (University of Oxford) presented work on antigen-specific CD4+ T follicular helper (Tfh) cell responses to RH5 in the two vaccine trials testing the ChAd63-MVA and protein/AS01B formulations. A negative correlation was observed between anti-RH5 IgG and IFNγ measured by ELISPOT, with higher IgG levels and lower IFNγ in the protein/AS01B platform. RH5.1/AS01B induced higher antigen-specific Tfh responses, which correlated with anti-PfRH5 IgG levels, RH5-specific memory B cells, and antibody functionality. A Th2 skew in the CD4+ T cell response was seen in the antigen-specific supernatant cytokine profile with the protein/AS01 platform that may be linked to an enhanced B cell response and IgG production. In contrast, a Th1 skew was seen with the ChAd63-MVA formulation.

**Thomas Lavstsen** (University of Copenhagen) finished the session with a talk on the status of vaccine development based on VAR2CSA and CIDRα1 PfEMP1, including findings from a phase I trial. The next steps for VAR2CSA vaccines are creating antigen decorated capsid particles (VLP) using bacteriophage ap205 or HPV for a clinical test of VAR2CSA-HPV vaccine. Antigenic variation is limited for CIDRα1, therefore it can be a prime target for vaccination. Mosaic VLPs will also be used to generate cross-reactive B cells.

**Simon Draper** closed the meeting by thanking the speakers and wishing everyone a relaxing evening to recover from an intense day.

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*This daily report has been written by Rebeca Santano and Robert Mitchell (ISGlobal) as part of the MESA Correspondents program. Senior editorial support and expertise have been provided by Dr Carlota Dobaño (ISGlobal).*
Day 2: 9th May 2019

SESSION 5: RECENT ADVANCES – SPOROZOITE AND LIVER-STAGE VACCINES

Sheetij Dutta (Walter Reed Army Institute of Research) opened the day with a presentation on studies determining in vitro and in vivo correlates of circumsporozoite protein (CSP) based immunotherapeutics. He defended that vaccines able to induce polyclonal responses that recapitulate the activity of monoclonal antibodies (mAbs) may be more cost-effective than deploying mAbs.

Ayman Khattab (University of Helsinki) presented how the N-terminal region of CSP may mediate immune evasion by hijacking the complement inhibitor protein complex C4bp. The N-terminal seems to provide a crucial function to the sporozoite and it is immunogenic, which points to a possible target to improve the RTS,S vaccine.

Alexandra J. Spencer (University of Oxford) presented strategies to induce high numbers of antigen-specific CD8+ T cells in the liver using IV administration of viral vectors. Using fine-needle aspiration in some volunteers, they were able to detect a population of T resident memory (Trm) cells in human livers following vaccination.

Daniel Jenkin (University of Oxford) followed on the vectored vaccines explaining a first-in-human challenge trial of prime-target immunization with liver-stage vaccine candidates ChAd63 and MVA ME-TRAP. Prime-target is a novel approach that induces immune memory and antigen specific lymphocytes in the liver, and it is mainly safe, despite some reactogenicity.

António M. Mendes (on behalf of the PbVac consortium) presented the results of the clinical trial of PbVAC, an engineered P. berghei parasite expressing P. falciparum CSP. Although no sterile protection was observed, PbVAC immunization delayed patency and decreased parasite density in all immunized volunteers. Immunization with PbVAC elicits functional PfCSP dependent antibody responses that inhibit P. falciparum sporozoite invasion of HC-04 liver cells.

Denise L. Doolan (James Cook University) closed this session with a presentation on systems-based approaches to define effective targets for interventions against malaria. She identified new immunoreactive antigens using a proteome-wide T-cell screening approach that can be used for T-cell target vaccine discovery, as well as antigens giving cross-species protective immunity. Machine learning approaches are also being applied to identify antigen signatures that can predict resistance or susceptibility to malaria.

SESSION 6: SPECIAL PATH/WHO SESSION

Mary Hamel (WHO, Geneva) led the special PATH/WHO session on the phased introduction and evaluation of the RTS,S/AS01 vaccine in children in Ghana and Malawi starting this past April, 2019, followed later by Kenya. This initial rollout of the vaccine has been approved by the governments of the participating countries. The 5-17 month old age group will be the focus with a dosing regimen at months 5, 6, and 7 in Malawi, at months 6, 7, and 9 in Ghana and Kenya, and all with a booster dose at 24 months. She discussed the value and impact of RTS,S/AS01 that has the potential to strengthen efforts to control malaria. Mary Hamel (speaking for Temwa Mzengeza, Ghana Health Service) reviewed the malaria burden in Malawi and the milestones of the Malaria Vaccine Implementation Programme (MVIP) where approximately 120,000 children per year will have the opportunity to receive RTS,S. The pilot will be accompanied by monitoring and evaluation by independent partners to determine the public health role of the vaccine. Patricia Njuguna (WHO) presented the procedures
for the evaluation of feasibility, safety, and impact of RTS,S in the pilot implementation studies. The first data are expected to be available 24 months after the pilots have started. Nekoya Otsyula (GSK Vaccines) presented an overview and the objectives of the evaluation component of MVIP by GSK and the requirements to allow for a broader use of the vaccine. She stressed that it is key to take timely decisions for long-term planning and avoid supply chain gaps. Margaret Gyapong (University of Health and Allied Science, Ghana) presented the need for monitoring within each country during the pilot period and gave specific examples from Ghana. She covered qualitative methods to evaluate vaccine pilot participation such as household surveys, and implementing “photovoice scenarios” where the primary caregiver takes pictures to reflect what the experience is like for them when the child receives the vaccine. Compliance of the full vaccination regimen and the underlying reasons will also be assessed. Finally, Mary Hamel (WHO, Geneva) wrapped up the session by reminding the audience that RTS,S is the first malaria vaccine going into use and that other candidates in the pipeline are needed to obtain improved vaccines. The lesson learned from an epidemiological perspective from the pilot implementation studies will also be beneficial for future vaccines.

SESSION 7: CELLULAR AND ANTIBODY VACCINE IMMUNOLOGY

Carlota Dobaño (ISGlobal, Barcelona Institute for Global Health) discussed qualitative aspects of antibody responses to malaria vaccines after primary and booster vaccination. She showed that the C-terminus of CSP is a target of immunity to RTS,S vaccine and that IgG avidity to this domain contributes to vaccine-induced protection. She emphasized the importance of the folding and glycosylation of the antigens, as well as measuring the subclass profile of IgG responses to identify correlates of protection. She also showed that RTS,S vaccination has an impact on vaccine-unrelated malarial antigens, which may affect the acquisition of natural immunity, vaccine efficacy and duration of protection.

Amy Flaxman (University of Oxford) continued on the theme of T cell immunogenicity in prime-target immunization with liver-stage malaria vaccines. She showed that the two dose heterologous prime-target enhances the immunogenicity and efficacy compared to two dose intramuscular prime-boost or three dose regime. This enhanced immunogenicity can be detected in the periphery and it is observed in the CD8+ T cell population.

Danika L. Hill (Babraham Institute, UK) presented results from the P27A malaria vaccine phase 1b trial, where the adjuvants Alhydrogel and GLA-SE were assessed. GLA-SE elicits stronger, long-lived IgG responses and promotes strong circulating Tfh cell expansion with shared TCR clonotypes among individuals.

Adrian Hill (on the behalf of Katie Ewer, University of Oxford) presented on the characterization of the antibody response to vaccination with R21/Matrix M. R21/MM was shown to elicit more potent and durable antibody responses at lower doses and associated with the induction of different Tfh cell populations, as well as higher memory B cell frequencies.

Simon J. Draper (University of Oxford) ended this session by emphasizing the importance of non-neutralizing human anti-RH5 mAbs, which potentiate the effect of neutralizing mAbs against malaria. This synergistic mechanism is based on the fact that the neutralizing anti-RH5 mAbs block the basigin binding, while the non-neutralizing mAbs slow merozoite invasion, but do not block it. Therefore, they allow for longer invasion time, giving the neutralizing mAbs more time to kill the parasite.
SESSION 8: STRUCTURE-GUIDED VACCINE DESIGN AND RECENT ADVANCES IN TRANSMISSION-BLOCKING VACCINES

Following on the previous session theme, David Pulido-Gomez (University of Oxford) discussed the characterization of antimalarial mAbs revealing synergistic epitopes in the *P. falciparum* Rh5-CyRPA-Ripr invasion complex. He covered the R5CyRP invasion complex mAb panel and stated that Class I mAbs able to bind to the R5CyRP complex can be GIA positive, whereas Class II mAbs do not commonly show GIA activity. Next, Matthew Higgins (University of Oxford) addressed the efforts to overcome the shortcomings of a PfRH5 vaccine using the information learned from the Rh5 vaccine mAbs studies to design improved vaccines using structure-guided knowledge. A redesigning of RH5 showed thermal stabilization and had the same binding, immunogenic and structural properties as the wild type RH5. Then, by computational immunogen grafting, an Rh5 immunogen was designed to prevent growth inhibition by 9AD4.

In relation to transmission blocking vaccine (TBV) development, David L. Narum (NIAID, NIH) presented an update on the Pfs230 and Pfs230-Pfs48/45 candidates. Pfs230D1M-EPA formulated with Alhydrogel induced functional activity in a study with US adults and contains at least two functional epitopes. Polymorphisms appear to be limited. Pfs230D1M(-EPA) alone or in combination provides a platform for TBV development. David Mekhaiel (University of Oxford) presented the Pfs48/45 vaccine candidate which is expressed from stage III gametocytes onwards and acts as an anchor for PfCCp complex. Pfs48/45 has advantages as an antigen target as it is relatively conserved and can be boosted with exposure. C. Richter King (PATH Malaria Vaccine Initiative) presented strategies for improving the potency and durability of TBV through structure-based vaccine design. The goal and challenge for next-generation vaccines is to produce durable cross-strain efficacy. Durable vaccine efficacy may not be achievable by recall responses since antibody levels must be at an effective concentration during exposure. To complete the TBV talks, Arianna Marini (University of Oxford) spoke about the HBsAg-based virus-like particles (VLPs) vaccine platforms and showed a promising, novel TBV candidate. In the plug-and-display technology the HBsAg is fused to SpyCatcher and decorated with various TBV antigens fused to SpyTag. The SpyCatcher::HBsAg platform allows the presentation of antigen in the orientation of choice and enhances the functionality of antigen specific antibody response. The response against the carrier did not have an impact on the antigen-specific response.

Rajagopal Murugan (German Cancer Research Centre) talked about maturation of potent cross-reactive antibodies to CSP in humans. His group showed that repeated *P. falciparum* exposure induced antibodies that cross-react to different CSP B cell epitopes, which are generated by gaining affinity to the N-terminal junction and NANP repeat region. The affinity of antibodies and the degree of cross-reactivity have an impact on the *P. falciparum* inhibitory capacity of antibodies.

The second day ended with a talk by Flavia Camponovo (Swiss TPH and University of Basel) on modelling and simulations to investigate different use scenarios for vaccines, namely for control, elimination, and prevention of malaria resurgence. She discussed some of the main objectives of using modelling and simulation such as determining the best time point for seasonal intervention or when conducting a mass intervention such as vaccination targeting the entire population.
SESSION 9: LATEST ADVANCES IN VACCINES AND CHMI FOR P. VIVAX

Hernando A. del Portillo (ISGlobal Barcelona Institute for Global Health) presented the potential for using reticulocyte-derived exosomes as a vaccine delivery platform against P. vivax and discussed novel antigen discovery. He demonstrated proof of concept in a rodent model and in human studies of plasma-derived vesicles from natural infections that showed the presence of parasite cargo associated with CD71+ EVs. These human reticulocyte-derived exosomes contain MHC Class I antigens that are actively taken up by myeloid dendritic cells and thus can be presented to the immune system.

Angela M. Minassian (University of Oxford) presented the establishment of a P. vivax sporozoite and blood-stage Controlled Human Malaria Infections (CHMI) in healthy UK adults. This is the first time that the mosquito-bite and blood-stage CHMI have been done in Europe. Using a characterized Thai isolate, the team has successfully established a new P. vivax blood-bank that will be available to the research community for CHMI. Next, they will carry out vaccine and immunology studies and prepare new blood banks for other Plasmodium isolates.

Chetan E. Chitnis (International Centre for Genetic Engineering and Biotechnology, New Delhi and Institut Pasteur, Paris) presented on the development of a vaccine designed to induce antibodies to block the interaction of PvDBP (Duffy Binding Protein) region II with DARC (Duffy-Antigen Chemokine Receptor), which is essential for P. vivax invasion of reticulocytes. The PvDBPII+GLA-SE vaccine was tested in malaria naive, healthy Indian adults and elicited strain transcending inhibitory antibodies. Next, Tom Rawlinson (University of Oxford) explained the molecular basis of the inhibition of P. vivax reticulocyte invasion by a vaccine-induced neutralizing human monoclonal antibody (mAb). This mAb was selected based on the performance on growth inhibition with transgenic P. knowlesi parasites expressing PvDBP and ex vivo invasion assays with Thai P. vivax clinical isolates. The team has also described the binding site of this mAb to DARC, suggesting that the binding to the epitope may hinder the interaction of PvDBP with DARC, preventing the invasion.

SESSION 10: NOVEL APPROACHES TO ANTIGEN DISCOVERY, VACCINE DELIVERY AND ADJUVANTS

Rana Chattopadhyay (Food and Drug Administration (FDA), USA) gave an overview of regulatory aspects relating to malaria vaccines by the U.S. FDA and provided an outline of the key regulatory stages and steps in vaccine development. He reviewed the need to demonstrate safety, effectiveness and manufacturing consistency for licensure, and stressed that there are opportunities to interact with the FDA at all stages of vaccine development.

Mark Howarth (University of Oxford) presented on bioconjugation techniques and capabilities via Spy Technology, like “bacterial superglue” that can accelerate malaria vaccine generation. SpyTag and SpyCatcher can be used in a variety of ways, such as SpyCatcher-mi3 protein capabilities for “Plug-and-Display” which creates a simple way to turn protein antigen into immunogenic VLPs (virus-like particles).

Evelina Angov (Walter Reed Army Institute of Research) presented a strategic overview of Walter Reed Army Institute of Research’s next generation adjuvanted P. falciparum circumsporozoite protein (CSP) vaccine candidates under clinical development. FMP013 is a soluble recombinant full length CSP. FMP014 is a self-assembling protein nanoparticle, recombinant with partial CSP sequences. Both are
formulated with the Army Liposomal Formulation + QS-21. Preclinical studies with these candidates in mice, rhesus macaques and rabbit show safety, good tolerability and immunogenicity.

Louise Bjerkan (University of Oslo) presented the Vaccibody, a DNA-based platform for antigen presenting cells (APC)-targeted vaccination against RH5. She showed that vaccination in mice induces IFNγ T cell responses to RH5 epitopes and RH5-specific neutralizing antibodies, which are efficient in blocking invasion of *P. falciparum* in growth inhibition assays. This platform can be translated into larger animals, and has shown to be safe in clinical trials in humans with other infectious diseases and cancer. She concluded that targeting RH5 to APC potentiates viral vector immunization against malaria.

Sarah E. Silk (University of Oxford) (on behalf of Ally Olotu (Health Institute and KEMRI-Wellcome Trust Research Programme)) presented the clinical trial assessing safety and immunogenicity of ChAd63 and MVA expressing *P. falciparum* RH5 in Tanzanian adults, young children and infants. The ChAd63/MVA RH5 appears to be safe and the trial will be unblinded soon.

Takafumi Tsuboi (Ehime University, Japan) stressed the need for novel malaria vaccine candidates and presented the innovative Japanese technology of wheat germ cell-free protein synthesis system in the context of vaccine development. With immunoscreening and functional approaches, he prioritized the blood-stage PfRipr protein, which showed to be a highly conserved top-rank vaccine candidate.

Paulo Bettencourt (University of Oxford) finished the session by discussing the identification of novel antigens presented by MHC (major histocompatibility complex) class I using immunopeptidomics platforms for potential vaccines against malaria. This new tool for antigen discovery has been able to identify a new family of antigens, the 40S and 60S ribosomal proteins as vaccine candidates. Homology between humans and *Plasmodium* ribosomal proteins is 60%, leaving the other 40% available for exploration.

**CLOSING REMARKS**

Simon J. Draper (University of Oxford) thanked the speakers, session chairs, poster presenters, and meeting management team. He gave a summary of the conference by comparing the topics covered this year 2019, with the content of the very first Malaria Vaccines for the World meeting in 2007 and commented on how remarkable the advances in the malaria vaccine field have been since then.
This daily report has been written by Rebeca Santano and Robert Mitchell (ISGlobal) as part of the MESA Correspondents program. Senior editorial support and expertise have been provided by Dr Carlota Dobaño (ISGlobal).
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