Department for Digital, Culture, Media & Sport

# Events Research Programme Phase II

## Development of Research Protocols

**Research Study Template:**

Study Name

Descriptive study of risk-mitigation with SARS-CoV-2 antigen rapid lateral flow testing to reopen live events

Event Locations for Study

Table 1. Characteristics of Phase 2 Events Research Programme pilot events with testing protocol.

| **Event** | England v NZ Test Match, Edgbaston, Birmingham | Royal Ascot Races, Ascot | Download Festival, Castle Donnington |
|---|---|---|---|
| **Dates** | 10-14 June | 15-19 June | 18-20 June |
| **Event capacity** | 18,000 (per day) | 12,000 (per day) | 10,000 (per day) |
| **% of venue capacity used** | 70% | 17% | 9% |
| **Simulation of full capacity** | Yes:<br>● Entry points running at full capacity with queues as normal.<br>● Seating bowl occupied in blocks of full stands, rather than checkerboard style.<br>● Every bar open and in use, with busy concourses.<br>● Hospitality areas with socially distanced tables in full use.<br>● Steady egress.<br>● City centre shuttle bus to/from event operating at full capacity with queues present. | Partial:<br>● Restaurants and fine dining at 75% capacity, with socially distanced tables.<br>● Hospitality boxes and members areas at full capacity.<br>● Outdoors areas at 20% capacity.<br>● 45-minute music event after the races – very crowded with no social distancing. | Yes:<br>● Queueing into event was at full capacity.<br>● Camping areas at full capacity.<br>● One main stage and one tent stage: to simulate full capacity the two stages did not have performers scheduled at the same time, therefore the tent stage was completely full when in use. Mosh pits and crowd surfing as normal.<br>● One other small cocktail bar which was busy at all times.<br>● Busiest day on site was Saturday (day 2) when all attendees had arrived.<br>● Toilets in between the two stages were at full capacity in the changeover between the two stages.<br>● Bars underused for first two days since attendees could bring their own drinks.<br>● Long queues for merchandise outlets and tattoo parlour. |
| **Setting description** | Large outdoor seated | Large outdoor, unstructured with fluid crowd movement | Large outdoor unstructured with fluid crowd movement, multi-day camping |
| **NPIs in use** | Face coverings to be worn when moving around the stadium | None | None |
| **Pre-event LFD test** | In the 36 hours prior to gates opening; 100% Universal Offer; At Home | | |
| **Pre-event PCR test** | In the 24 hours prior to gates opening | | |
| **Post-event PCR test** | On day 5 following the last day attended | | |

Principal Investigators

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Key research question(s)

1. What proportion of those who attend the events:

    a. complete a pre-event lateral flow device (LFD) test,
    b. return a completed pre-event home test PCR kit,
    c. return a completed post-event home test PCR kit, and
    d. return both completed pre-event and post-event home test PCR kits?
2. What proportion of those who attend the events:
    a. receive a PCR positive test result indicative of them attending the event already infected (i.e. index cases), and
    b. receive a post-event PCR positive test result and is suspected to be a secondary case (e.g. pre-event PCR negative test result)?
3. Using whole genome sequencing of positive home test PCR kits:
    a. how many likely secondary (event-transmitted) cases were detected with post-event PCR tests and are linked by their genomic sequencing results, and
    b. can genomic sequencing of pre-event PCR positive tests identify a linked index case?
4. Using Contact Tracing Advisory Service (CTAS) data:
    a. how many of the ERP-related cases report that they attended an event during their infectious (index cases) or incubation (secondary cases) periods,
    b. is the information reported sufficient to support rapid outbreak detection, and
    c. are the thresholds for common exposure and postcode coincidence alerts sufficient to support rapid action?

Link to a published protocol for Phase I (if relevant)

https://www.gov.uk/government/publications/events-research-programme-science/descriptive-and-feasibility-study-of-risk-mitigation-with-sars-cov-2-antigen-rapid-lateral-flow-testing-to-reopen-live-events

Study Design

This is an observational study comparing SARS-CoV-2 PCR test positivity pre- and post-attendance at an ERP event (both Phase 1 and 2).

Every eventgoer will undertake a LFD test in the 36 hours prior to the event. Only those able to demonstrate a negative test result, and declaring no symptoms, will be permitted entry to the event. If an LFD test is positive, the eventgoer must not attend the event and, in accordance with national guidance, they must self-isolate and take a confirmatory PCR test. To assess the effectiveness of pre-event LFD testing in identifying those infected with SARS-CoV-2 and the potential for transmission having occurred at the event, eventgoers will also be asked to provide a home PCR test on the day of the event and a home PCR test five days after the event. All positive PCR tests with a Ct value of less than 30 will be genome sequenced to identify clusters of SARS-CoV-2 infections, indicating potential transmission at the event.

Any positive tests will be reported through Test and Trace and contact tracing undertaken to ascertain detail of activity during the day of the event including travel, seating and activity at the venue.

The event organisers will send a list of all eventgoers who attended the event to PHE, using secure transfer methods. Eventgoer information (self-reported name, date of birth, sex, full address, email address and phone number) will be linked to NHS number using the Demographic Batch Service. NHS number will be used to link to the Pillar 2 testing dataset, for the time-period from 36 hours prior to 7 days following the event. A 7-day post-event cut-off will be used to capture those who might receive a positive result earlier (e.g. if they become symptomatic) and those who might return their sample late. Genomic sequencing data linkage will occur at a later timepoint.

If an NHS number cannot be matched via the Demographic Batch Service, probabilistic data matching techniques will be used to attempt to link eventgoer information to the Pillar 2 testing dataset. Eventgoer data linkage will be performed with other datasets to allow the use of socio-demographic and other data (such as ethnicity, vaccination and deprivation data).

CTAS data will be extracted and analysed for each case to assess data completeness and whether thresholds for triggering common exposure or postcode coincidence alerts were met.

Phase 2 data will be obtained, processed, stored and analysed alongside Phase 1 data, in accordance with information governance protocols. Personal identifiers will not be stored, and data will be analysed using unique identifiers attached to record level data.

Results will be published in anonymised format.

The analyses are descriptive in nature, and no formal power size calculation is presented. The study population will be between 37,000 and 106,000 people, depending on whether eventgoers attend over multiple days or buy only single day tickets.

Key outcome measures

1. Pre-event LFD test result linked – yes/no
2. Pre-event LFD test result – positive/negative/void
3. Pre-event PCR test result linked – yes/no
4. Pre-event PCR result – positive/negative/void
5. Sequencing results for pre-event PCR positive cases
6. Post-event PCR test result linked – yes/no
7. Post-event PCR result – positive/negative/void
8. Sequencing results for post-event PCR positive cases
9. Event name, postcode and date reported to CTAS – yes/no
10. CTAS common exposure or postcode coincidence alert triggered – yes/no

The full statistical analysis plan for Phase 2 will be reported separately, and will be similar to that developed for Phase 1. The Phase 1 statistical analysis plan can be found here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/991447/ERP_Transmission_SAP_v2.7.pdf

NPIs in use

Detailed in Table 1.

Engagement with participants and communications

Communications relating to testing are developed and delivered by DCMS, DHSC and the event organisers.

Peer Review

This protocol was reviewed and approved by the Events Research Programme Science Board on 2nd July 2021.

Ethics Approval

Granted by PHE Research Ethics and Governance Group on 16/04/21, R&D 437.