

# Delivering COVID-19 Vaccine Trials at Speed: The ComFluCOV Experience

Baos S<sup>1</sup>, Lazarus R<sup>2</sup>, Todd R<sup>1</sup>, Thirard R<sup>1</sup>, Kirwan J<sup>1</sup>, Joyce K<sup>1</sup>, Hutton D<sup>1</sup>, Harris R<sup>1</sup>, Culliford L<sup>1</sup>, Clout M<sup>1</sup>, Cappel-Porter H<sup>1</sup>, Rogers CA<sup>1</sup>  
 1) Bristol Trials Centre, University of Bristol, Bristol, UK; 2) University Hospitals Bristol & Weston NHS Foundation Trust, Bristol, UK



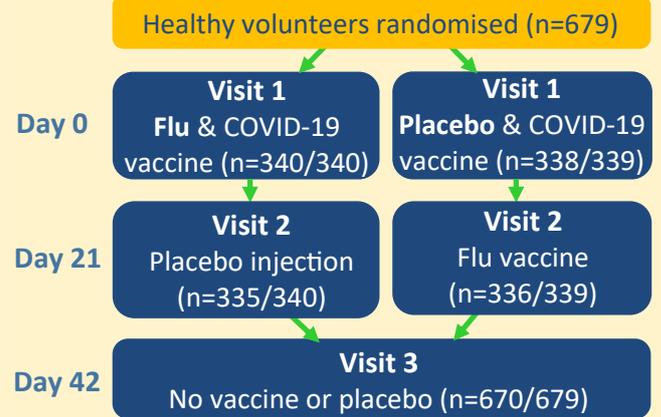
## Background:

- In December 2020 COVID-19 mass vaccination started
- COVID-19 booster doses were necessary & the timing was likely to coincide with seasonal flu vaccination
- Giving both vaccines at same time could increase vaccine uptake & reduce appointments
- In February 2021 the Department of Health & Social Care (DHSC) wanted data to inform the September 2021 vaccination policy
- Most trials are delivered over several years but Bristol Trials Centre (BTC) had 6 months to deliver this one

## Aim:

To determine the safety & immune responses of administering COVID-19 & flu vaccines at the same time

## Design: Parallel-group, placebo-controlled RCT



- Side effects reported on e-diaries daily
- Blood collected at all visits to assess immunity

## Timelines, Milestones & Delivery:



## How did we deliver in 6 months?

- Large team (11 BTC staff)
- Over busy periods staff worked >70 hours/week
- Fast-track approvals (urgent public health status)
- Study materials adapted from previous COVID-19 trials
- Prompt vaccine supply
- Use of advertising/media for recruitment
- CRN screened volunteers
- Online training (>380 staff)
- 12 recruiting sites
- Electronic management & data capture systems
- Daily data review
- Weekly trial management & site meetings



**Results showed that it is safe to receive the COVID-19 & flu vaccines at the same time.** ComFluCOV informed World Health Organisation & UK immunisation policy. Practice has been implemented in the UK.

Image from HM Government, NHS 'Boost your immunity this winter' 2021 campaign

## Main findings:

Rapid delivery of vaccine trials is feasible in a pandemic situation:

- CTU enabled immediate mobilisation of an experienced team
- Fast-track regulatory & governance processes were essential
- Altruism & media publicity were key to recruitment

## Increasing efficiency of future trials:

- Greater resource sharing between CTUs
- Wider use of electronic systems for site management e.g. e-delegation logs
- Virtual meetings



FUNDED BY



This trial was funded by the National Institute for Health Research Policy Research Programme (PR-R17-0916-22001, NIHR203243). The views in this article are those of the authors and not necessarily those of the UK Department of Health and Social Care.