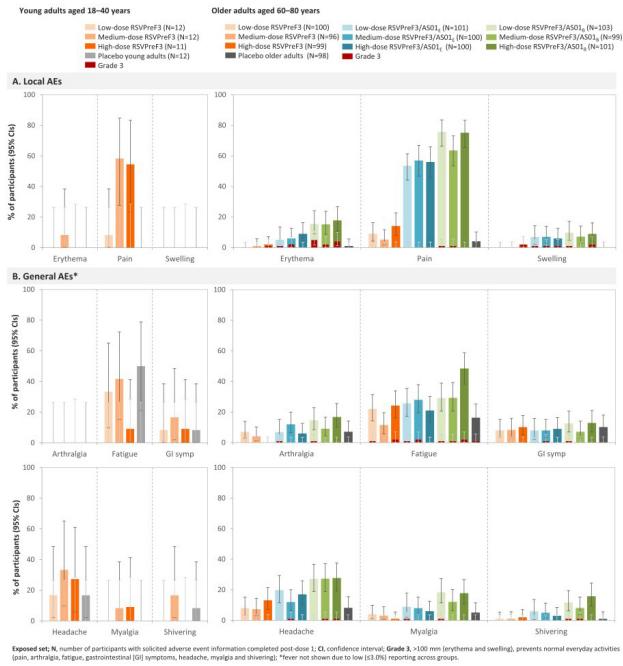


Figure 2. Percentage of participants with at least one type of solicited adverse event (AE) within 7 days post-dose 1



Exposed set; N, number of participants with solicited adverse event information completed post-dose 1; CI, confidence interval; Grade 3, >100 mm (erythema and swelling), prevents normal everyday activities (pain, arthralgia, fatigue, gastrointestinal [GI] symptoms, headache, myalgia and shivering); 'never' not shown due to low (<3%) reporting across groups.

**Conclusion:** First dose of RSVPreF3 candidate vaccine is well tolerated. AE rates tended to be higher after AS01<sub>B</sub>-adjuvanted formulations compared to other vaccine formulations. No safety concerns were raised.

**Funding:** GlaxoSmithKline Biologicals SA

**Disclosures:** Jelena Tica, PhD, GSK group of companies (Employee, Shareholder) Javier Ruiz Guiñazú, MD MSc, GSK group of companies (Employee, Shareholder) Charles P. Andrews, MD, GSK group of companies (Scientific Research Study Investigator) Charles Fogarty, MD, GSK group of companies (Grant/Research Support) Edward Kerwin, MD, Amphastar (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)AstraZeneca (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Boehringer Ingelheim (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Chiesi (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Cipla (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)GSK group of companies (Employee, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)GSK group of companies (Employee, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Mylan (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Novartis (Employee, Advisor or Review Panel member, Research Grant or Support, Speaker's Bureau)other around 40 pharmaceutical companies (Other Financial or Material Support, conducted multicenter clinical research trials)Pearl (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Sunovion (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Theravance (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)Isabel Leroux-Roels, MD PhD, GSK group of companies (Scientific Research Study Investigator) Corinne Vandermeulen, MD PhD, GSK group of companies (Other Financial or Material Support, My university only received Grant/Research Support) Marie-Pierre David, MSc, GSK group of companies (Employee, Shareholder) Nancy Dezutter, PhD, PharmD, RPh, GSK group of companies (Employee, Shareholder) Laurence Fissette, MSc, GSK group of companies (Employee) Julianne Koch, MD, GSK group of companies (Employee, Shareholder) Narcisa Mesaros, MD, MSc, GSK group of companies (Employee)

## 120. Impact of a Molecular Point-of-care 'test and Treat' Strategy for Influenza in Hospitalised adults: A Multi-centre, Randomised Controlled Trial (FluPOC)

Tristan William. Clark, BM MRCP DTM&H MD<sup>1</sup>; Kate Beard, BMBS<sup>2</sup>; Nathan J. Brendish, PhD<sup>3</sup>; Ahalya Malachira, MD<sup>3</sup>; Samuel Mills, BM BCh<sup>4</sup>; Cathleen Chan, MBBS<sup>5</sup>; Stephen Poole, BMBS<sup>3</sup>; Sean Ewings, PhD<sup>1</sup>; Nick Cortes, MBBS<sup>6</sup>; Esther Nyimbili, n/a<sup>7</sup>; Laura Presland, n/a<sup>7</sup>; <sup>1</sup>University of Southampton, Southampton, England, United Kingdom; <sup>2</sup>University of Southampton, Southampton, England, United Kingdom; <sup>3</sup>University Hospitals Southampton NHS Trust, Southampton, England, United Kingdom; <sup>4</sup>University Hospital Southampton Foundation NHS Trust, Southampton, England, United Kingdom; <sup>5</sup>University Hospital Southampton Foundation NHS Trust, Southampton, England, United Kingdom; <sup>6</sup>Hampshire Hospitals Foundation NHS Trust, Basingstoke, England, United Kingdom; <sup>7</sup>NIHR Southampton Biomedical Research Centre, Southampton, England, United Kingdom

**Session:** O-23. Hot Clinical Trials

**Background:** The diagnosis of Influenza in hospitalised patients is delayed due to long turnaround times of laboratory testing, leading to inappropriate and late antiviral and isolation facility use. Molecular point-of-care test (mPOCT) are highly accurate,

easy to use and generate results in under 1 hour but high quality evidence for their clinical impact is lacking.

**Methods:** In this multicentre, randomised controlled trial we enrolled adults hospitalised with acute respiratory illness during influenza seasons. Patients were randomised (1:1) to receive mPOCT for influenza or routine clinical care. The primary outcome was the proportion of influenza-infected patients who received antivirals. Secondary outcomes included time to antivirals, isolation facility use, and clinical outcome. This study is registered with ISRCTN, number:17197293, and has completed.

**Results:** Between December 2017 and May 2019, 613 patients were enrolled (307 assigned to mPOCT and 306 to routine care) and all were analysed. 100 (33%) of 307 patients in the mPOCT group and 102 (33%) of 306 in the control group had influenza. 100 (100%) of 100 influenza-infected patients were diagnosed in the mPOCT group and 60 (59%) of 102 were diagnosed through routine clinical care (relative risk 1.7, 95%CI 1.7 to 1.7; p<0.0001). 99 (99%) of 100 influenza-infected patients received antivirals in the mPOCT group versus 63 (62%) 102 in the control group (relative risk 1.6, 95%CI 1.4 to 1.9; p<0.0001). Median time to antivirals was 1.0 hour in the mPOCT group versus 6.0 hours in the control group (difference of 5.0 hours, 95%CI 0 to 6.0; p=0.004). 70 (70%) of 100 influenza-infected patients in the mPOCT group were nursed in single room accommodation versus 39 (38%) of 102 in the control group (relative risk 1.8, 95%CI 1.4 to 2.4; p<0.0001). Median hospital recovery scale score (an ordinal 6 point scale used to assess patient outcome) at 7 days was lower in the mPOCT group versus the control group (p=0.045).

Figure 1a: Time-to-event curve showing antiviral use over time in influenza-infected patients.

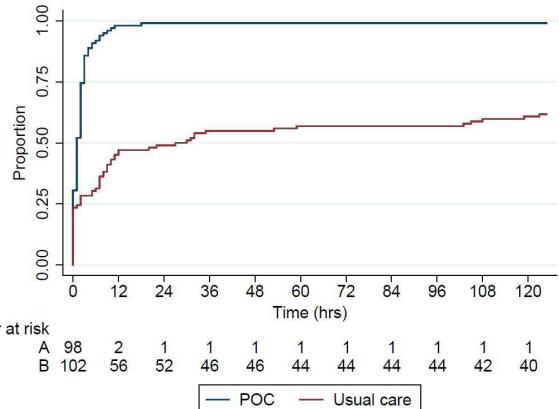
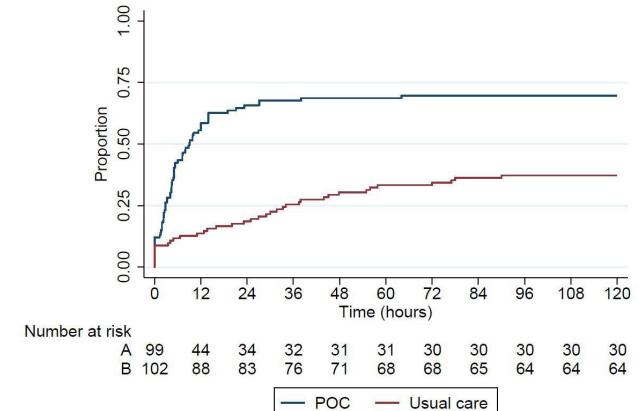


Figure 1a: Time-to-event curve showing antiviral use over time in influenza-infected patients.



**Conclusion:** Routine mPOCT for influenza was associated with enhanced influenza detection, improvements in appropriate and timely antiviral and isolation facility use, and more rapid clinical recovery.

**Disclosures:** Tristan William. Clark, BM MRCP DTM&H MD, BioFire Diagnostics (Other Financial or Material Support, Equipment and consumables for the purposes of research)BioMérieux (Other Financial or Material Support, Equipment and consumables for the purposes of research)Qiagen (Other Financial or Material Support, Discounted Equipment and consumables for the purposes of research)

## 121. A Respiratory Syncytial Virus Prefusion F Protein (RSVPreF3) Candidate Vaccine Administered in Older Adults in a Phase I/II Randomized Clinical Trial Is Immunogenic

Javier Ruiz Guiñazú, MD MSc<sup>1</sup>; Jelena Tica, PhD<sup>1</sup>; Charles P. Andrews, MD<sup>2</sup>; Matthew G. Davis, MD<sup>3</sup>; Philippe De Smedt, MD<sup>4</sup>; Brandon Essink, MD CPI<sup>5</sup>; Charles Fogarty, MD<sup>6</sup>; Edward Kerwin, MD<sup>7</sup>; Isabel Leroux-Roels, MD PhD<sup>8</sup>,