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| **Unit** | COVID-19 Unit: Lesson 6 | | | | **Driving Question** | “How do vaccines get approved?” | |
| **Date** |  | | **Time** |  | **Class** |  | |
| **Real life scenario (context)** | | | | | | | |
| James’s aunt Sarah has now submitted the data she collected during the clinical trials for the new COVID-19 vaccine. It is now your role to look at this data and decide whether it can be approved for public use or not. What criteria will you use? | | | | | | | |
| **Learning Outcomes** | | | | | | | |
| 1. Identify the regulatory body (FDA in the US) for vaccines.  2. Analyse datasets to better understand criteria used by researchers during clinical trials.  3. Explain the role of the regulatory body in approving a vaccine, the criteria used, and also the continued role post-approval. | | | | | | | |
| **NGSS links / NYAS STEM Education Framework (key skills and competencies developed)** | | | | | | | |
| A.1.6 Data Literacy  A.2.1 STEM Mindset  B.3 Real-world Application | | | | | | | |
| **Plan of activities** | | | | | | | |
| Time | | Teacher Activity | | Learner activity | | | Resources / other info |
| *Prior to session: -* | | *Are there spare activities for those who finish early?* | | *Can this be done remotely and in person? Are there alternative approaches?*  *Differentiation?* | | | *What resources are needed to be inclusive to all students?* |
| **5 mins**  Intro and review | | Introduce LOs and review the clinical trials process. Identify for the students the role of the FDA in this process. | | Students read the scenario for context, review the clinical trials process and identify the FDA (Food and Drug Administration) as the US regulator. | | | PPT  Note: teacher to note that every country has its own regulator. |
| **20 mins**  Introduction of the role of the FDA through talking about the child immunisation schedule | | Introduce the role of the FDA explaining to students that one of their roles is to approve vaccines on the immunisation schedule (see table on slide 4). Then play video and discuss questions after – “think, pair, share”.  Answers to slide 5:  FDA - Food and Drug Administration  Lots - vaccines are made in batches called ‘lots’ which are tested for quality and safety.  Immunisation schedule - approved vaccines for various diseases which people are expected to get at a certain age (usually in childhood).  FDA looks across all data gathered in the clinical trials and looks at safety and efficacy. FDA continued to monitor (e.g. through VSD and PRISM systems) for side effects after vaccine approval. | | Students recognise the role of FDA as already having approved vaccines that they themselves are certain to have taken as a child. Students that watch the FDA video and make notes so that the answers can be discussed afterwards (either as a class or in pairs). | | | Immunisation schedule from CDC ([PDF](https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf))  [Video](https://www.youtube.com/watch?v=Fcvgp6gNh6o&feature=youtu.be) from CDC about how vaccines are approved and added to the immunisation schedule. |
| **30 mins**  Data task – students take on the role of clinical researchers to analyse data for phase 2 clinical trials for a Covid-19 treatment (mock dateset). | | Teacher should then connect FDA back to COVID-19 approval vaccine (again stressing that the same process was taken, same safety and efficacy criteria, just in a condensed time frame).  Teacher introduces a data task for students as students look through data collected from just one part of the clinical trials (in this case, phase 2) and discuss in their groups whether or not they would have ‘approved’ this treatment to progress to clinical trial phase 3.  As students are completing the task, the teacher should be asking some prompt questions (see slide 7) to get students to think about what the data is telling us (or not) and the evidence that students are basing their decisions on. Again, as in lesson 5, it’s important to stress to students that clinical trials are not a ‘one-way street’ and can be stopped if there are significantly severe adverse effects (in a significant frequency) identified (and causally linked to the vaccine upon investigation).  Teacher will identify one student from each group to share their group’s decision and rationale. Teacher should remind students that there isn’t necessarily a ‘right’ answer and many of the decisions taken are about weighing up the evidence and balancing risk and benefits (a ‘risk management’ approach). | | Students will engage with a dataset from clinical trial (phase 2) that mirror those that COVID-19 vaccines went through. In groups, students must discuss the reasons for approval or not in reference to the data that have. Students will use the workstreet which helps to ‘scaffold’ their answers.  One student from each group must be prepared to share with the rest of the class what their group's decision was and defend their decision (as other students will have a chance to ask questions as they potentially may have arrived at a different conclusion). Students should also be encouraged to discuss the level of ‘risk’ that is acceptable and weigh that against the potential benefits of developing a drug/vaccine for the target population (in the case of Covid-19, target is everyone). | | | There is a ‘teacher’ and ‘student’ dataset (Excel files) and worksheets. Whereas this mock dataset is just for clinical trial phase 2, stress that the FDA would look at ALL the data across all phases (we have reduced the dataset for accessibility).  Note: The dataset does not involve ethnicity for a smaller/more accessible dataset but it may come up as a discussion point so it’s important to stress that in real life, clinical trials are larger and do involve volunteers from diverse populations and there was a [particular effort](https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-diversity-within-covid-19-vaccine-clinical-trials-key-questions-and-answers/) made with Covid-19 vaccine clinical trials to ensure that these trials were more representative of the general population (sadly, it has been a historical problem in the scientific community). Finally, it is important for students to understand that there is no ‘clear cut’ answer to some of the questions faced by drug/vaccine approval bodies who have to look at all the data and balance out risk with benefits to the target population (risk management approach). |
| **5 mins**  Plenary | | Teacher to wrap up with a plenary ‘exit ticket’ based on the scenario. | | Students complete an exit ticket – handing in individually on paper or sending in via email / private chat function if virtual lesson. | | |  |
| **Total time = 60 mins** | |  | |  | | |  |
| **Preparation for next lesson (teacher self-reflection) Gather student feedback to**  **incorporate into your next session** | | | | | | | |
| Which aspects of the lesson went well? Which aspects could be improved upon?  What misunderstandings still need to be cleared up?  Actions for the future: | | | | | | | |