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| **Unit** | COVID-19 Unit – Lesson 5 | | | | **Driving Question** | “How do we ensure vaccines are safe and effective?” | |
| **Date** |  | | **Time** |  | **Class** |  | |
| **Real life scenario (context)** | | | | | | | |
| James’s aunty Sarah works as a medical researcher involved in developing new medicines and new vaccines. Sarah is currently designing clinical trials for the new COVID-19 vaccine – what criteria should she be using to develop a new vaccine? | | | | | | | |
| **Learning Outcomes** | | | | | | | |
| 1. Recognize the importance of clinical trials in developing vaccines (and more widely medicines).  2. Describe the different stages of clinical trials (pre-clinical, phase 1,2,3).  3. Explain why placebos are used in clinical trials. | | | | | | | |
| **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 recap | | Teacher introduces the LOs and sets the context. Previous lesson was talking about different vaccines – now how did vaccines get developed in the first place? | | Students read the scenario and understand that the key question is about making sure vaccines are both **safe** and **effective** and that there are **standard procedures (clinical trials)** to ensure this. | | | PPT |
| **5 mins**  Video explaining main stakeholders in clinical trials | | Introduce the role of clinical trials (ensuring safety, effectiveness) and key stakeholders (sponsor, Contract Research Organisations (CROs), investigators, patients) by showing the video. | | Students identify the main stakeholders by watching the video. Students will take the role of the professionals working at the CRO who will be ‘designing’ the clinical trial. | | | <https://drive.google.com/file/d/1YPWPk3C0bXGIidgGB_q4MWgGtMB0f82U/view> (first 2 mins) |
| **15 mins**  Students role play being a scientist in a CRO designing a clinical trial (using the flashcards). | | Teachers explain how students will role-play scientists working at the CRO who will be designing the clinical trials.  Provide the flash cards for students. Before students start the activity, teachers should explain what **placebo** means. Teacher can then choose to do this as a group or individual exercise. After the answers are revealed, teacher should ask what criteria is used to go to the ‘next’ stage. | | Students have to rearrange the flash cards (needs to be cut pre-lesson or simply put up slide 5 if virtual lessons) – they have 5 minutes to decide on the right order.  After the answer is revealed, students should discuss what they think the criteria is at each stage of the clinical trials (e.g. looking for positive or adverse health outcomes and any side effects. Constant monitoring). | | | Flashcards  NOTE: Teachers can easily spread out these lessons over a longer time. Should there be interest and time available, activities demonstrating the placebo effect and also ‘double-blind’ trials can be found here: <https://www.stem.org.uk/resources/elibrary/resource/27185/placebo-effect>  <http://www.centreofthecell.org/wp-content/uploads/Double_Blind_Trials.pdf> |
| **10 mins**  Clinical trial key words/stages | | Show the [video](https://www.youtube.com/watch?v=rrFA3lZAAuo) (till 3.32) and ask students to focus on the key words:   1. Placebo 2. Double-blind 3. FDA (what does it stand for) 4. Phase 1 5. Phase 2 6. Phase 3 | | Students watch the video and write down definitions/details around the 6 key words regarding clinical trials. In particular, students should focus on the role of each of those key words in the process (and understand that the process is not unidirectional – there are ‘dead ends’). | | | This [video](https://www.youtube.com/watch?v=rrFA3lZAAuo) is needed.  Bonus question is with regards Phase 4 – ask students to guess what this phase can refer to. It’s important students understand that even after FDA approval, once the drug or vaccine is being used by the public, there is ongoing monitoring of the effects. |
| **20 mins**  Case study of COVID-19 vaccine using reading exercise of an article from Nature | | Teachers hand out the [article](https://www.nature.com/articles/d41586-020-03626-1) (or simply share the link to the article in the science journal *Nature*).  Students should practice reading articles of a scientific nature - in this case, for the reasons why the COVID-19 vaccine was developed within a year. Ask students to circle anything they aren’t sure of so that the teacher knows what to explain/go back on.  In the last 5 minutes, go through the reasons but also ask students what they think would happen if adverse side effects were identified during the clinical trials (it would pause, be investigated to see if linked to the vaccine and potentially the trials could be halted).  Teachers should also be aware that questions around ethnicity may also crop up (given historical issues with underrepresentation in trials). Important to say [intentional efforts](https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-diversity-within-covid-19-vaccine-clinical-trials-key-questions-and-answers/) were made to ensure that Covid-19 vaccine clinical trials involved diverse populations. This issue may also crop up in lesson 6. | | Students read through the article highlighting or writing down the reasons why the COVID-19 vaccine was developed so fast. Reasons include:   * International cooperation (e.g. in sequencing the COVID-19 virus genome) * Urgency of the global pandemic – a ‘new’ pathogen having drastic effects * Amount of money (usually funding shortage is an issue) * Building on prior research and technology (e.g. the ‘plug and play’ technology of the Oxford-AZ vaccine which was developed for Ebola) * Running clinical trials concurrently. * No shortage of volunteers (public wanted to play their part).   Students should also circle anything in the article that they don’t understand and share this with the teacher. | | | [Article](https://www.nature.com/articles/d41586-020-03626-1) for the Journal *Nature*.  NOTE: This gets to the heart of one of the concerns regarding the COVID-19 vaccine. Yes, the speed of the development of the COVID-19 vaccine is much faster than previous vaccines but it is important to stress that there are reasons behind this and also that no clinical trial steps or approval steps were ‘skipped’. Many were simply condensed due to the urgency of the pandemic.  It’s also important that students understand that clinical trials are not unidirectional and don’t have a guaranteed ‘ending’. In fact, most drugs/vaccines don’t get to market as they fail these stringent clinical trials. |
| **5 mins**  Plenary | | Teacher should ask students to complete their ‘exit ticket’ based on the scenario question. | | Students write down their exit ticket and give to the teacher or type into the chat box (send directly to the teacher). | | | Students should also hand in (or email) their articles with any circled parts needing explaining. |
| **Total =60mins** | |  | |  | | |  |
| **Preparation for next lesson (teacher self-reflection) Gather SS 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: | | | | | | | |