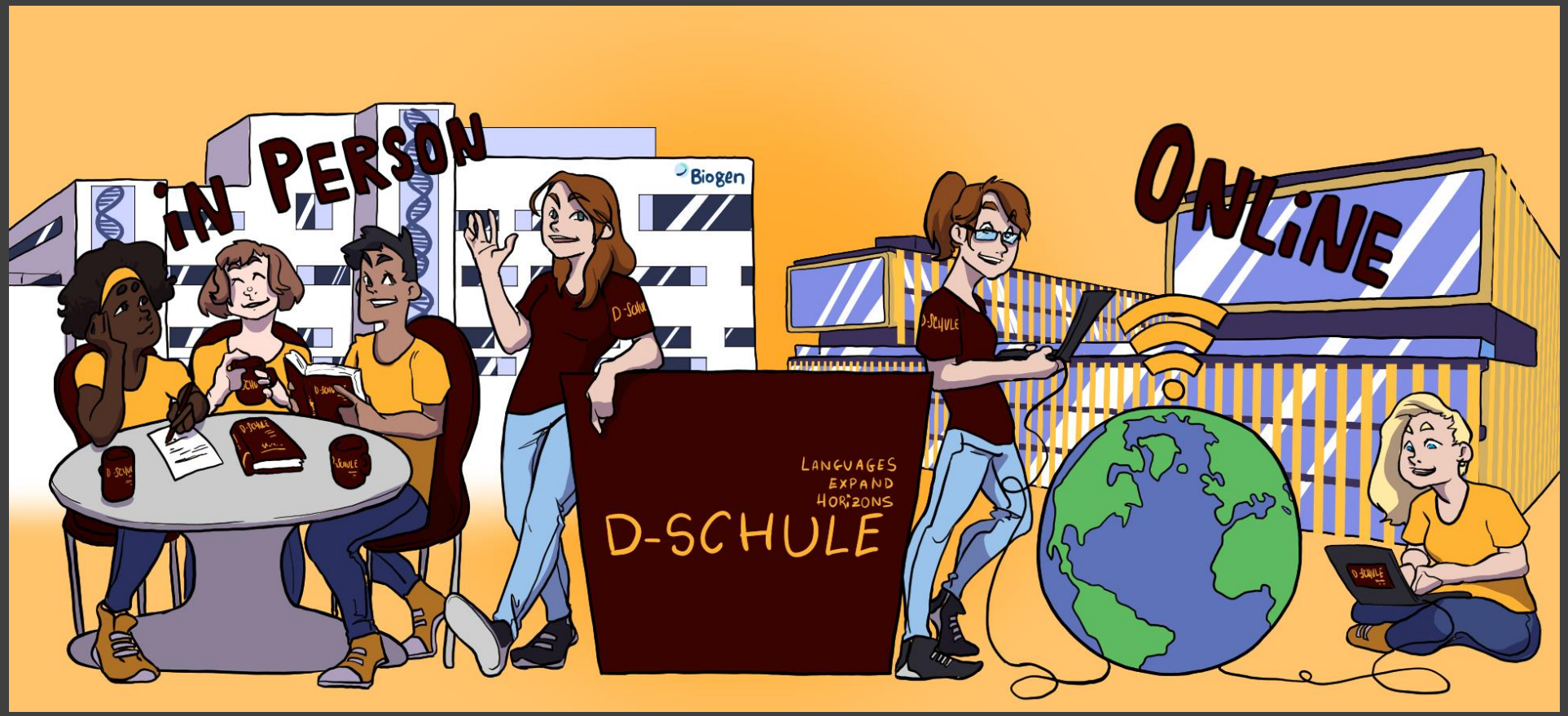
Biogen Specific Teaching Material

EMA – European Medicines Agency



Questions & Answers

1. What did the European Medicines Agency (EMA) use to be called?

EMA – European Medicines Agency

1. The European Medicines Agency (EMA) used to be called the European Agency for the Evaluation of Medicinal Products (EMEA).

2. What is the EudraVigilance?

2. It is the European registry for drug safety notifications.

3. How is the European Commission involved with the EMA?

3. It makes scientific assessments of issues with regard to marketing authorization applications.

4. What is the EMA responsible for?

EMA – European Medicines Agency

4. The EMA is responsible for the evaluation and monitoring of medicinal products and the maintenance and promotion of public health within the European Union.

5. What is another duty of the EMA?

5. The EMA is additionally responsible for the continuous monitoring of safety of medicinal products already authorized in the EU.

6. What is Pharmacovigilance?

6. It is the science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. (or drug safety)

7. Is the EMA responsible for the scientific evaluation, monitoring, safety reviews and approval of medicinal products for human and veterinary medicine?

7. Yes, the EMA handles both human and veterinary medicinal products within the EU.

8. How many countries is the EMA responsible for coordinating? 3 - 13 - 30

8. The EMA is responsible for the coordination of all 30 European states.

9. The EMA uses scientific resources from which organisations?

9. It collaborates with both the National Competent Authorities (NCA) and European Economic Area (EEA).

10. Which two international bodies does the EMA have ties with?

10. The EMA works together with the ICH and the VICH on drug approval conditions.

11. What is European Economic Area (EEA) and what role does it serve?

11. The European Economic Area (EEA) is an agreement (made in 1992) that brings the European Union (EU) member countries and three of the European Free Trade Association (EFTA) states—Iceland, Liechtenstein, and Norway—into a single market.

Thank you for your attention!

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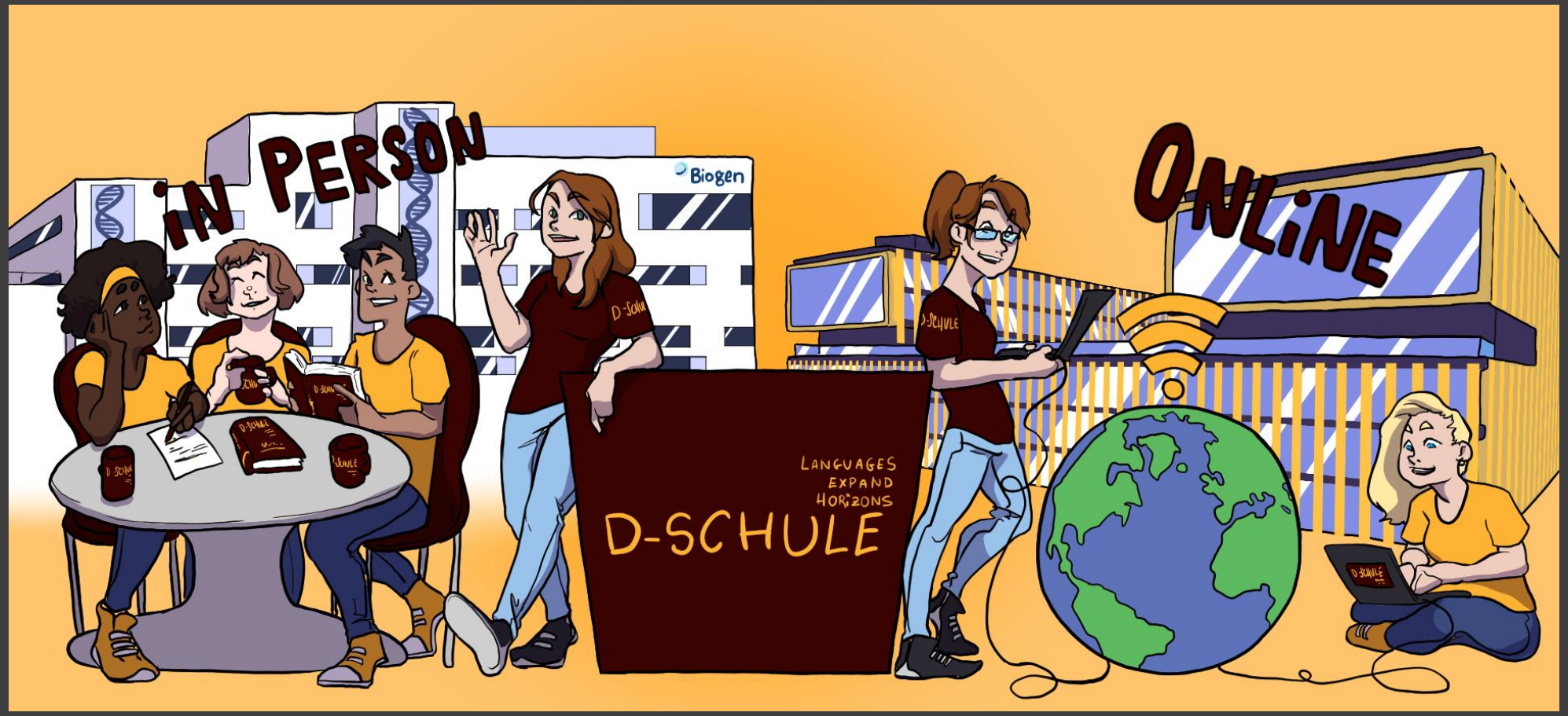

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