

Global Vaccine Minimum Dataset

- The Learning Health Community has collaborated with CDISC to develop a minimum set of key data elements for documenting vaccinations¹
- FDA will submit comments to this initiative
 - This is **not** to set a standard for any data submitted to the FDA
 - FDA is not testing this minimum dataset

¹<https://www.cdisc.org/events/education/webinars/2021/05/public-review-webinar-vaccination-administration-record-minimum>

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- Objectives
 - To achieve an agreement of a minimum set of data elements
 - To enable the success of vaccine credentialing applications
 - To secure sharing information for uses such as safe travel

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Core data elements

Patient	Vaccine	Vaccine Administration	Certificate
Person Identifier	Disease or agent targeted	Dose number	Entity that has issued the certificate
First and last name	Vaccine/ Prophylaxis	Date of dose	Certificate Identifier
Date of Birth	Medicinal Product name	Batch/Lot Number	Certificate valid from
Sex/Gender	Manufacturer	Next Vaccination Date (optional)	Certificate valid to
	Vaccine property – number in a series of vaccinations/ doses	Administering Center/Site	

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