COVID-19 Vaccine basic interview questions

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| **Vaccine candidate identity** |
| Promoter |  |
| Vaccine candidate |  |
| GMO | (yes/no) |
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| **Platform type and antigens** |
| Description of the platform (inactivated, attenuated vaccine, viral vector, subunit, DNA, RNA, other) |  |
| Use of adjuvant? which one? |  |
| Previous experience with this platform for other pathogens (which ones, which clinical phase, commercial vaccine?) |  |
| Use of non-standard technology for vaccination (e.g. electroporation) |  |
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| **Preclinical development phase** |
| Availability of preclinical testing results showing induction of an immune response to CoV-2-SARS (if yes, in which animal model?) |  |
| Availability of pre-clinical testing results showing protection against SARS-CoV-2 (if so, in which animal model?) |  |
| Demonstration of risk minimization for disease exacerbation by immune mechanisms (in animal models, which one)? |  |
| Have the preclinical results been published (reference)? |  |
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| **Clinical development to date** |
| Description of regulatory strategy |  |
| Proposed vaccination schedule (one or two products, number of doses, prime-boost?) |  |
| Target populations (in order of priority) for future vaccination |  |
| If not yet in Phase 1, time required to initiate clinical trials |  |
| Already completed/ongoing clinical trial(s) with the same vaccine candidate, in which populations |  |
| Countries involved |  |
| Results obtained (reference if publication)  |  |
| Choice of vaccine dose and of vaccination schedule for efficacy studies |  |
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| **Vaccine production and strategic evaluation** |
| Validation of clinical batch manufacturing processes already done/to be performed? |  |
| Speed (and simplicity) of the production cycle (x weeks, months)? |  |
| Maximum production batch size (in number of doses) |  |
| Production capacity in 2020 (in number of doses) |  |
| Annual production capacity from 2021 (in number of doses) |  |
| Geographic location of large-scale vaccine production sites |  |
| Industrial partnership envisaged for large-scale production |  |
| Current Intellectual Property and *Freedom to Operate* |  |
| Current contractual partnership framework |  |
| Secured financial resources and funders |  |
| Other international collaborations envisaged |  |
| Vaccine dose reservation capacity for France/Europe and number of doses |  |
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| **Clinical studies proposed in France (when relevant)** |
| Phase  |  |
| Trial design |  |
| Flexibility in the design of the proposed protocol  |  |
| Primary and Secondary Objectives |  |
| Evaluation Criteria |  |
| Expected number of participants |  |
| Characteristics of the participants | *Age groups* |
|  | *Possible clinical features* |
| Testing for SARS-CoV-2 negativity | *…* |
| Biological samplesroutinebiobanking, PBMC banking |  |
| Number of countries already involved in the trialWhich ones? |  |
| Other countries in which the trial could be conducted |  |
| Scientific advice requested from regulatory agencies | *National Agencies**EMA* |
| Estimated date of submission for regulatory approval |  |
| Desired start of recruitment |  |
| Acceptable duration for inclusions |  |
| Dynamic inclusion calculation (nb VS/week) | *To be calculated* |
| Duration of participant follow-up (months) |  |
| Request for other collaborations (immunomonitoring, data management, methodology, biostatistics, etc.). |  |
| GMP batch production | *Compagnie* |
| Post-trial and *fill & finish* vaccine production | *Compagnie* |
|  |  |
| **Next phase of development and AMM filing** |
| Clinical trial Phase  |  |
| Forecasted date for development phase |  |
| Countries considered for hosting the following clinical phases |  |
| Estimated date for submission of marketing authorisation application |  |
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