

# National COVID-19 Vaccination Strategy

Strategy to Introduce and Evaluate a Vaccine against Sars-CoV-2 in Germany

Last updated: 06 November 2020



# Contents

- Background ..... 3
- 1. Overview: Covid-19 vaccines and vaccine development ..... 5
- 2. Covid-19 vaccine approval..... 6
- 3. Vaccine recommendations and vaccine requirements ..... 7
- 4. Production and procurement..... 8
- 5. Distribution, storage and logistics ..... 8
- 6. Organising and implementing vaccinations ..... 9
- 7. Financing..... 10
- 8. Communication, specialist training and public information..... 11
- 9. Vaccine rate monitoring..... 11
- 10. Surveillance: Evaluating the safety and efficacy of Covid-19 vaccines ..... 12
  - 10.1. Vaccine efficacy ..... 13
  - 10.2. Vaccine safety ..... 14
- 11. International coordination and cooperation..... 15

## Background

The development and widespread use of safe and effective Covid-19 vaccines is seen as a realistic option for ending the current pandemic and controlling SARS-CoV-2 infection rates in the longer term. Vaccination enables immunity to be achieved in large parts of the population. The aim is to counter the spread of the virus and reduce the potential health-related consequences of Covid-19 infections. Developing a new vaccine is, however, challenging and can take months or even years.

The objective is to provide safe and effective vaccines as soon as possible and in sufficient quantities. More than 200 different Covid-19 vaccine candidates, some on the basis of novel vaccine platforms, are currently being developed. **Yet, it remains unclear as to which of these candidates will successfully pass preclinical and clinical trials all the way through to approval. It furthermore remains unclear when these vaccines will be available in sufficient quantities to enable their broad public use.** The first Phase 3 trials to demonstrate efficacy and safety with different vaccine candidates were approved in July 2020. It has been announced that approval applications for two or three vaccine developments will be submitted to the European Medicines Agency later this year.

The Federal Government of Germany is actively engaged in the procurement of vaccines to be able to provide sufficient quantities of a reliable vaccine with the ultimate aim to offer them the entire population once they have been approved. To start with, however, it is likely that only limited quantities of different vaccines will be available. As a result, in its vaccination recommendations, the Standing Committee on Vaccination at the Robert Koch Institute (STIKO) calls for the **prioritisation of specific population groups who should be vaccinated first**. Given the initial prioritisation of target groups, the limited number of vaccine doses and the potentially challenging product properties of certain vaccines (e.g. storage and transport conditions, filling of the vaccine into multi-dose containers), it makes sense **in a first phase to conduct the vaccinations in central vaccination centres supported by mobile teams**. As soon as sufficient quantities of a vaccine are available, the aim is to transfer vaccination activities to the regular healthcare system.

In light of the pandemic situation, the use of novel vaccine platform technologies, high public expectations and the fact that several vaccines with different product properties will no doubt be used simultaneously, **proactive communication and scientific support** is needed to ensure safe and successful implementation of the COVID-19 vaccination strategy.

This document sets out the key components of a national Covid-19 vaccination strategy and describes the systems which will ensure vaccination of the German population according to uniform standards along with timely evaluation of the vaccines during their broad application.

It serves as a guide, assists planning and allows for possible gaps that may still exist to be addressed by the responsible stakeholders. Table 1 gives an overview of the components of and stakeholders involved in the holistic vaccination strategy.

Table 1: Overview – Elements of a holistic vaccination strategy and relevant stakeholders

<b>Components</b>	<b>Stakeholders</b>
<b>Vaccine development</b>	Federal Ministry of Education and Research (BMBF), universities, pharmaceutical companies
<b>Vaccine approval</b>	Paul Ehrlich Institute (PEI), European Medicines Agency (EMA) and the European Commission, pharmaceutical companies
<b>Vaccine recommendations and prioritisation</b>	Standing Committee on Vaccination at the Robert Koch Institute (STIKO), Robert Koch Institute (RKI), Leopoldina (National Academy of Sciences), German Ethics Council
<b>Production and procurement</b>	European Commission, EU member states, BMBF, Federal Ministry for Economic Affairs and Energy (BMWi), BMG, pharmaceutical companies
<b>Distribution, storage and logistics (supply chain management)</b>	BMG, Federal Ministry of Defence (BMVg)/German Armed Forces, Länder governments, logistics companies, pharmaceutical wholesalers, (hospital) pharmacies
<b>Organisation and implementation of vaccination activities</b>	Länder governments, Public Health Service (ÖGD), National Association of Statutory Health Insurance Physicians (KBV), Länder-level associations of SHI-accredited physicians (Kassenärztliche Vereinigungen der Länder), medical personnel
<b>Financing</b>	BMG, Länder, Statutory Health Insurance Funds (GKV), Private Health Insurance Funds (KV)
<b>Communication, specialist training and public information</b>	Federal Centre for Health Education (BZgA), RKI, PEI, BMG, Länder, Academy of Public Health Services, specialist associations
<b>Vaccine rate monitoring</b>	RKI
<b>Surveillance of vaccine efficacy and vaccine safety</b>	RKI, PEI, EMA, pharmaceutical companies
<b>International coordination and cooperation</b>	Federal Government, EU, scientific forums
<b>Lessons learnt</b>	Federal Ministry of Health

# 1. Overview: Covid-19 vaccines and vaccine development

Vaccine development spans across different phases, from the explorative and pre-clinical phase with trials on laboratory animals, to clinical phases 1, 2 and 3 with trials on humans, to marketing authorisation and market introduction.

Figure 1: Overview of the phases of vaccine development



After producing a potential vaccine candidate in the research laboratory, initial **animal and cell culture experiments** are conducted to assess whether, in addition to its tolerability, it is suitable for producing a protective effect against the target pathogen or the infectious disease caused by it, where an animal model exists for this purpose. Subsequently, toxicological and pharmacological properties are evaluated in various animal models. Only when there is no doubt as to its safety for use on humans is a first **clinical trial** performed to assess its safety on healthy human adult volunteers (Phase 1). In the subsequent **clinical trial phases**, the optimal dosage and vaccination schedule are tested in a larger number of volunteers (several hundred) (Phase 2) and then the efficacy and side-effect profile of the vaccine are determined in a large, randomised, controlled clinical study (Phase 3) with several thousand volunteers from different age groups.

Several novel vaccine candidates (e.g. mRNA and DNA vaccines) are currently being developed and clinically tested on different manufacturing platforms. **The Federal Government promotes vaccine research and production and, seeing it as a global responsibility, advocates fair global distribution of vaccines.**

Table 2 lists the Covid-19 vaccine candidates for which, according to the current status of knowledge, marketing authorisation is being sought in the EU and for which early availability may be possible or a sufficient number of vaccine doses could be made available to begin a nationwide vaccination campaign for prioritised groups.

- The Federal Government (BMBF, BMG) promotes research activities.
- Pharmaceutical companies and research institutes develop vaccines.

Table 2: Overview of vaccine candidates and current status of development (manufacturer's information, as of November 2020), subject to change

Company	Vaccine Type	No. of Doses Vac- cination Inter- val*	Vaccine Vol- ume Application*	Status: Clinical Development	Planned ap- plication for EU approval
Oxford/ Astra- Zeneca	Vector-based ChAdOx1, not replicating	(1-)2 doses 0, 28 days	1 dose à 0.5ml IM	Phase 1/2: UK Phase 3: UK, Brazil, South Africa, India, US	Start of Roll- ing Review October 2020
BioN- Tech/ Pfizer	mRNA coated in lipid-nanoparti- cles	2 doses 0, 21 days	1 dose à 0.3ml IM	Phase 1/2: DE, US Phase 3: US, Brazil, Ar- gentina, Turkey, DE	Start of Roll- ing Review October 2020
J&J/Jans sen	Vector-based Ad26, not replicating	(1-)2 doses 0, 56 days	1 dose à 0.5 ml IM	Phase 1/2: BE, US Phase 2: DE Phase 3: Global	2021
SP/GSK	Recombinant, ad- juvanted	2 doses 0, 28 days	1 dose à 0.5ml IM	Phase 1/2: US Phase 3: US	2021
Modern a/ Lonza	mRNA coated in lipid-nanoparti- cles	2 doses 0, 28 days	1 dose à 0.5ml IM	Phase 3: US	Possibly end 2020
Novavax	Recombinant, ad- juvanted	2 doses 0, 21 days	1 dose à 0.5 ml IM	Phase 1: Australia Phase 2: US, Australia, South Africa Phase 3: UK	Possibly end 2020
Curevac	mRNA coated in lipid-nanoparti- cles	2 doses 0, 28 days	1 dose 0.6% IM	Phase 1: BE, DE Phase 2: Peru, Panama	Unknown

\*Note: Preliminary information based on current knowledge

## 2. Covid-19 vaccine approval

Approval of the Covid-19 vaccine candidates listed in Table 2 for all EU member states is to be granted by the European Commission following a centralised assessment procedure coordinated by the EMA. An approval procedure is used to demonstrate the efficacy, pharmaceutical quality and safety of the vaccine, thus ensuring that the **products administered to patients** are of **appropriate quality** and demonstrate a **positive risk-benefit ratio**.

It is possible that Covid-19 vaccines could be evaluated as part of an accelerated procedure. However, even under accelerated approval procedures, the efficacy, pharmaceutical quality and safety of the vaccine as well as a positive risk-benefit ratio must nonetheless be proven. Individual data packages may also be submitted to the EMA for evaluation as soon as they are available (**rolling review**).

If sufficient data is available to assess the quality, efficacy and safety of a vaccine in terms of its risk-benefit ratio, the Committee for Medicinal Products for Human Use will recommend to the EMA that it be approved if the risk-benefit ratio is favourable. Based on that recommendation, the European Commission grants EU-wide approval.

The first data packages for rolling review have already been submitted in the EU. Assuming that a favourable risk-benefit ratio can be confirmed, the first approvals are expected in Q1/2021 at the earliest.

The Paul Ehrlich Institute tests vaccine batches before they are placed on the market and approves them for release in Germany in accordance with section 32 of the Medicinal Products Act (AMG).

- Marketing authorisation for Covid-19 vaccines at EU level is usually granted by the European Commission.
- The Paul Ehrlich Institute tests vaccine batches and approves their release in Germany in accordance with section 32 of the Medicinal Products Act (AMG).

### 3. Vaccine recommendations and vaccine requirements

Based at the Robert Koch Institute, the **Standing Committee on Vaccination (STIKO)** in its capacity as a legally established commission has the task of drawing up and issuing vaccine recommendations for Germany. While the safety, efficacy and quality of a new vaccine are the main focus of the approval process, STIKO decides how an approved vaccine can best be applied within the population. This goes beyond an individual risk-benefit assessment and also takes in the potential effects on the population (e.g. maximum reduction in the number of deaths or a reduction in virus transmission) into account.

**All STIKO recommendations are based on a detailed and thorough evaluation of the available evidence.** In particular, this includes the assessment of risk factors (for infection or serious illness) and the safety and efficacy of the vaccine.

When vaccinating against Covid-19, it can be assumed that in the beginning, there will not be sufficient vaccine quantities available to meet overall needs. Priority should thus be given to defining risk groups (e.g. staff in residential care homes and medical staff, senior citizens, persons with existing diseases) who are especially vulnerable or have a particularly high risk of exposure or are involved in transmitting the virus in some specific way and who should be vaccinated first. **Prioritisation of the target groups is based on epidemiological and ethical criteria, and both the German Ethics Council and the National Academy of Sciences Leopoldina will be consulted.** An initial vaccination recommendation is currently being prepared and will be finalised as soon as data is made available from the Phase 3 vaccine trials.

It is possible that SARS-CoV-2 will continue to cause illness in the population even after the pandemic, so that vaccination against Covid-19 may also be necessary in the longer term (in the post-pandemic phase).

- STIKO is working on a recommendation for the use of available, approved Covid-19 vaccines.
- The recommendation will be continuously adapted and aligned in accordance with the current status of evidence and the available vaccines.
- Initially, it will be necessary to prioritise groups of persons who should be vaccinated first. STIKO, in collaboration with the German Ethics Council and the Academy of Sciences Leopoldina, is developing ethical guidelines to aid that prioritisation.

#### 4. Production and procurement

To ensure the timeliest availability of Covid-19 vaccines in sufficient quantities in Germany, the Federal Government procures vaccines centrally via a joint EU procurement mechanism. In the event of promising R&D projects, **advance purchase agreements are agreed with manufacturers.**

These agreements ensure that citizens have early access to successfully tested, safe vaccines as soon as they are approved for use in the EU. They also enable manufacturers to build up production capacity in line with scientific development of the vaccines, allowing faster supply and delivery following approval.

The EU has already secured access to as many as **800 million doses for the EU population from various manufacturers.** These doses will be distributed to the EU member states in proportion to their respective populations. Some vaccine manufacturers have announced that the first deliveries of vaccine doses to EU member states may be possible before the end of 2020, provided that the vaccines are authorised for marketing in the EU.

- BMG/Federal Government procure Covid-19 vaccines via a common EU procurement mechanism. As part of that process, Germany is participating in the EU Commission's Vaccine Initiative.

#### 5. Distribution, storage and logistics

**Proper and safe transport** is necessary to ensure that the potential Covid-19 vaccines reach those to be vaccinated in all 16 German states undamaged and intact.

During planning, special requirements for transport and storage conditions must be taken into account: **Certain vaccine candidates** (e.g. mRNA vaccines) require **special storage conditions** (e.g. cool chain, temperatures < -60°C). It is also expected that the vaccines will be delivered in multi-dose containers and that required vaccination accessories (syringes,



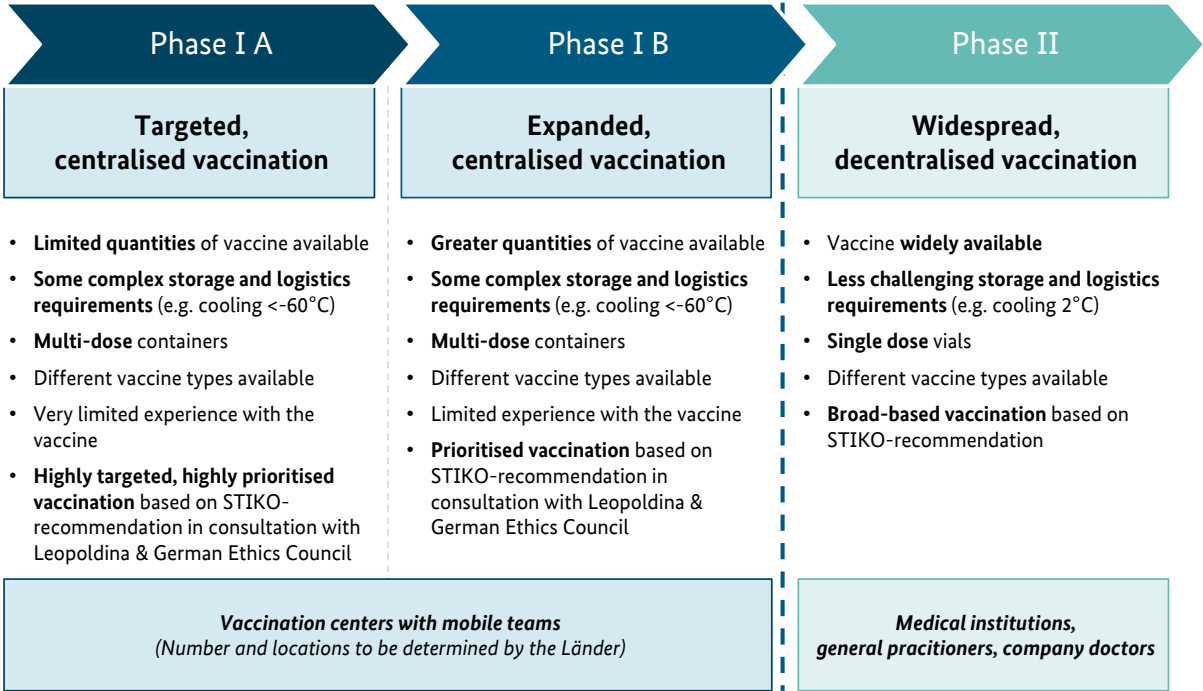
cannulas) and any necessary solvents (e.g. 0.9% NaCl solution) will not be included in delivery. As a result, the provision of vaccination equipment and any necessary solvents should be ensured by the Länder (federal states).

The agreements the EU Commission has reached with the vaccine manufacturers so far stipulate that the manufacturers deliver vaccine doses to central locations in EU member states. In Germany, vaccine doses will be distributed to central locations designated by the Länder proportionate to the population of the respective state. BMG is currently examining a range of options to ensure safe distribution of the vaccines to the various Länder.

- BMG/Federal Government organise the distribution of possible Covid-19 vaccines to designated locations in each state.
- The Länder are responsible for correct and safe storage and distribution of vaccines at local level, and for procuring and maintaining stocks of the necessary vaccine equipment and supplies.

## 6. Organising and implementing vaccinations

Figure 2: Organisation and implementation



Given the special circumstances surrounding the pandemic, in a first phase vaccinations against Sars-CoV-2 will be carried out in **vaccination centres to which mobile vaccination teams may also be assigned**. As already mentioned, the reasons behind this approach are the special transport and (long-term) storage requirements, vaccine supply in multi-dose containers, the need for prioritisation in the event of initial limited availability of vaccine doses, the expected availability of different vaccines and the need for increased

control measures, including centrally organised data-supported monitoring of vaccinations as a component of pandemic management. Under these conditions, centralised structures facilitate a vaccination campaign that is controlled, efficient and effective.

For centralised Covid-19 vaccinations, the Länder are responsible for organising and setting up the vaccination centres. They will set up and operate them with the support of general practitioners, in particular the Länder-level SHI-accredited physicians associations (Kassenärztliche Vereinigungen) and, where appropriate, medical staff from hospitals or other institutions. Preparation and implementation can be supported by other external stakeholders such as aid organisations, the German Armed Forces and logistics companies.

**As soon as the conditions allow** and sufficient quantities of vaccine are available with suitable storage conditions, the aim is to **transfer vaccination activities to the regular supply system** (decentralised via pharmacies, GPs and company doctors).

- The Länder are responsible for organising and setting up the vaccination centres and for ensuring that the vaccines are properly distributed to and administered to those in the priority vaccination groups with the involvement of local stakeholders.

## 7. Financing

**Potential Covid-19 vaccines are to be made available free of charge.** Financing of Covid-19 vaccination in vaccination centres should be made simple and effective to achieve high vaccination rates and speedy vaccination.

It is planned that after consulting STIKO and the German Federal Association of Health Insurance Funds (Spitzenverband Bund der Krankenkassen), BMG will issue a statutory order stating that persons with statutory health insurance and also persons without statutory health insurance are entitled to receive a Covid-19 vaccination. With this approach, BMG ensures timely access to the vaccination programme for the group of persons covered by the STIKO recommendation.

To promote rapid set-up and smooth, lean-management procedures in the vaccination centres, the running costs incurred are to be invoiced in the form of a lump-sum amount. **The costs of setting up and organising vaccination centres are to be borne jointly by the Länder and using funds from the statutory health insurance funds (health fund's liquidity reserve) and, where appropriate, the private health insurance funds.** The Federal Government supplies the vaccination centres with the federally-procured vaccines without the need for refinancing.

- BMG issues a statutory order on proportional financing by the statutory health insurance funds.

## 8. Communication, specialist training and public information

In the course of the pandemic so far, proactive communication with the public and target group-specific information campaigns have contributed significantly to both the acceptance and the implementation of measures to deal with the pandemic (e.g. the AHA-formula (based on the German for “masks, hand-washing, distance”) for the general public and the testing strategy specialists). A transparent, proactive and targeted communication campaign is of particular importance to foster the vaccination strategy’s success.

To ensure uniform and targeted communication, a federal level **Communications Management Committee** featuring among others, BMG, BZgA, PEI and RKI has been set up. Management of communications on Covid-19 vaccination, including development of the structure and the schedule, is the responsibility of the executive level at the Ministry of Health. The aim is to coordinate and harmonise the overall measures, including PR work, addressing target groups such as healthcare staff, vulnerable groups and the general public. From the outset, the focus is placed on transparency and on involving and communicating with significant social groups.

- Establishment of a Communications Management Committee under the leadership of BMG.

## 9. Vaccine rate monitoring

Valid data on vaccination uptake (**vaccination rates**) **provides the basis for analysing vaccination behaviour and the success of the accompanying information campaign**. Information on target group-specific vaccination rates enable both management and adaptation of the vaccination strategy. For example, the information campaign can be adapted if vaccination rates are particularly low in certain population groups or if there are large regional differences between the Länder. The vaccination rates also serve as a **“common denominator” in classifying efficacy and safety** (differentiating between individual cases versus representative cases based on the total number of all persons vaccinated) (see Section 10).

For the purpose of vaccination rate monitoring, the following non-personal data is required:

- Details concerning the person receiving the vaccine – age, gender, place of residence (Land/district), indications concerning the vaccinated person
- Details concerning the vaccination – place of vaccination, date of vaccination, vaccine product (name and batch number), vaccination dose administered (first vaccination or follow-up vaccination where applicable)

In order to ensure both **timely analysis of and transparency in** the implementation of Covid-19 vaccinations, the **vaccination centres must forward this data to RKI, preferably**

**in real time.** A web-based data portal is to be used for this purpose. The portal is to be developed by RKI prior to the launch of the vaccination campaign in Germany.

In addition to online real-time documentation and reporting, other components will enable integrated monitoring of vaccination rates in Germany (Table 3). The outputs will be made available to other stakeholders (BMG, PEI, BzgA, the Länder) in aggregated form.

Table 3: Components of an integrated approach to vaccination rate monitoring in Germany (As of: 04 November 2020)

Components	Description
<i>Central, online system</i>	<ul style="list-style-type: none"> <li>Near-real time documentation and reporting of non-personal data on take-up (vaccination rates): All vaccination centres must collect the minimum dataset and transmit it in aggregated form</li> <li>System being developed by RKI</li> <li>High data protection standards and statutory instrument as a basis</li> </ul>
<i>Regular, representative population surveys</i>	<ul style="list-style-type: none"> <li>14-day surveys in the form of a representative sample of the population</li> <li>Survey preparation by RKI</li> <li>The minimum dataset enables collection of the reasons for non-vaccination, vaccination intention and vaccination acceptance</li> </ul>
<i>Documenting the vaccination status of hospital staff using OkAPII</i>	<ul style="list-style-type: none"> <li>Adaptation of the OkAPII system (originally created to record influenza vaccination rates) to Covid-19 vaccination with a shortened survey interval of one month</li> <li>Documenting the Covid-19 vaccination status and surveying vaccination acceptance/vaccination barriers in the core target group of hospital staff</li> </ul>
<i>RKI vaccination surveillance using health insurance fund data</i>	<ul style="list-style-type: none"> <li>Established and legally-embedded routine system for vaccination rate monitoring based on health insurance fund data</li> <li>Not suitable for Phase I of pandemic vaccination in vaccination centres as based on individual invoices and a delay of 3-6 months</li> <li>In the transition to the decentralised routine vaccination system (Phase II): Use of the system based on health insurance fund data to validate the data from online real-time monitoring (in addition, estimation of vaccination efficacy, duration of vaccination protection, long-term adverse effects)</li> </ul>

- RKI is responsible for monitoring the vaccination rates.
- RKI develops an online vaccination rate monitoring system for nation-wide use in vaccination centres and by mobile teams.
- RKI designs and conducts parallel studies and surveys on vaccination rate monitoring.

## 10. Surveillance: Evaluating the safety and efficacy of Covid-19 vaccines

When new Covid-19 vaccines are introduced, **active surveillance of the safety and efficacy of the vaccine product(s) is absolutely essential.** Large clinical trials on the clinical efficacy and safety of the vaccines are ongoing worldwide and are being evaluated for approval. **Only vaccines with a proven positive risk-benefit ratio will be approved and made available.** Due to the fast development and the limited duration of observation in

the trials, continuous monitoring and collection of further data during widespread use is necessary to identify any potential risks caused by the vaccines as quickly as possible.

**Vaccine benefit and risk assessment is a continuous process** ranging from vaccine development, to pre-approval clinical trials to post-marketing surveillance. While pre-marketing clinical trials provide important information on the safety and efficacy of vaccines, post-marketing studies are essential to obtain further information on the safety and efficacy of the vaccine (e.g. occurrence of rare adverse effects) in larger and more heterogeneous populations that have not been studied in pre-approval clinical trials.

Post-marketing surveillance of the efficacy, safety and also the duration of protection of vaccines ensures that the positive risk-benefit profile established at the time of approval can be continuously reviewed as the vaccine becomes widely used and that vaccination recommendations can be adapted where needed to reflect the new findings.

Table 4: Overview of the proposed systems and studies for use in evaluating vaccine efficacy and safety in Covid-19 vaccinations in Germany

	Data collection in real time or near-real time	Data collection in the medium and longer term
<i>Vaccine efficacy</i>	<ul style="list-style-type: none"> <li>• Case reports under the Protection against Infection Act (IfSG) (breakthrough infections)</li> <li>• Screening methods</li> </ul>	<ul style="list-style-type: none"> <li>• Hospital-based case-control studies (efficacy, period of protection)</li> <li>• Outbreak studies as cohort studies</li> </ul>
<i>Vaccine safety</i>	<ul style="list-style-type: none"> <li>• Routine pharmacovigilance (individual-based reporting)</li> <li>• Cohort studies, including app-based</li> </ul>	<ul style="list-style-type: none"> <li>• Hospital-based case-control studies</li> <li>• Evaluation of digital health data</li> <li>• Surveillance of pregnant women</li> </ul>

10.1. Vaccine efficacy

As part of the reporting obligation under the Protection against Infection Act, information on reported Covid-19 cases, including the vaccination status, is transmitted to the Robert Koch Institute. In the short term, by **comparing the proportion of vaccinated persons among the Covid-19 cases reported (breakthrough infections) with the proportion of vaccinated persons in the population**, it is possible to estimate the efficacy of the vaccination (screening method).

In the longer term, a **hospital-based case-control study** will be used to measure the efficacy of Covid-19 vaccines used in Germany by including Covid-19 patients (vaccinated and unvaccinated). In particular it will look at protection in exposure to hospitalised or severe cases of Covid-19 infection, the duration of protection provided and whether in relation to these parameters there are differences between the available vaccines.

**Outbreaks** in special facilities (e.g. care institutions, community facilities) or at events where the group of exposed persons can be easily defined should also be investigated using a standardised methodology and data collection tools. In such settings, depending on the institution involved and especially as regards particularly vulnerable groups, the efficacy of vaccination can be determined as part of a retrospective cohort study.

## 10.2. Vaccine safety

**Routine pharmacovigilance** is based on established real-time monitoring of possible side effects or vaccination-related complications in accordance with sections 6, 8 and 11 of the Protection against Infection Act (IfSG) and section 63 (c) of the Medicinal Products Act (AMG) predominantly based on individual-based reporting.

In the short term, a **cohort study using a smartphone app** will prospectively track the frequency and severity of adverse effects and of SARS-CoV-2 infections in vaccinated adults over a period of one year.

In the longer term, the **hospital-based case-control study** to investigate the efficacy of vaccination in hospitalised Covid-19 patients (vaccinated and unvaccinated, see 10.1) will also investigate the **severity of the clinical course of the infection** and **look for possible indications that could suggest a worsening of the infection following vaccination**.

Furthermore, an **evaluation of digital health data** on the safety of Covid-19 vaccines will also be conducted. The electronic data from four large health insurance funds, which cover about 70% of statutory insured persons in Germany, will serve as a basis. Data on potential risk signals from Phase 1-3 studies and new risk signals detected during widespread use after approval are examined on a quarterly basis. Modelling and AI methods are used to estimate the risks for subsequent quarters. In the design phase, an assessment should be made as to whether and, if necessary, how in order to aid these evaluations the performance and billing data could be linked with the data recorded at the time of vaccination.

To study the safety of the vaccines in the vulnerable group of pregnant women, most of whom are not included in pre-marketing clinical trials **surveillance of pregnant women will** be conducted (pregnancy complications in pregnant women who have been vaccinated shortly before or during pregnancy – such as abortion, premature birth, stillbirth and eclampsia, compared with unvaccinated pregnant women – fetal malformations, low birth weight, postnatal adaptation disorders compared to non-exposed newborns).

- Within the scope of their remits, the higher federal institutions RKI and PEI actively shape the monitoring of efficacy and safety of COVID-19 vaccines.

## 11. International coordination and cooperation

The SARS-CoV-2 pandemic is a challenge of global scale. Coordination and cooperation with international partners is thus an essential component of the vaccination strategy in order to accelerate the development of and access to effective and innovative responses and solutions.

The German Federal Ministry of Health works closely with its partners in the European Union on the joint procurement of vaccines. It also maintains regular bilateral and multi-lateral exchange with various other stakeholders.

BMG is actively involved in various international forums and promotes cooperation between stakeholders from the foundation system as well as from the public and private sectors. In addition, BMG, in collaboration with the respective authorities, provides support within the boundaries of their remit (RKI and PEI) to aid the international transfer of knowledge. This includes, among others, the project and committee-based work outlined below.

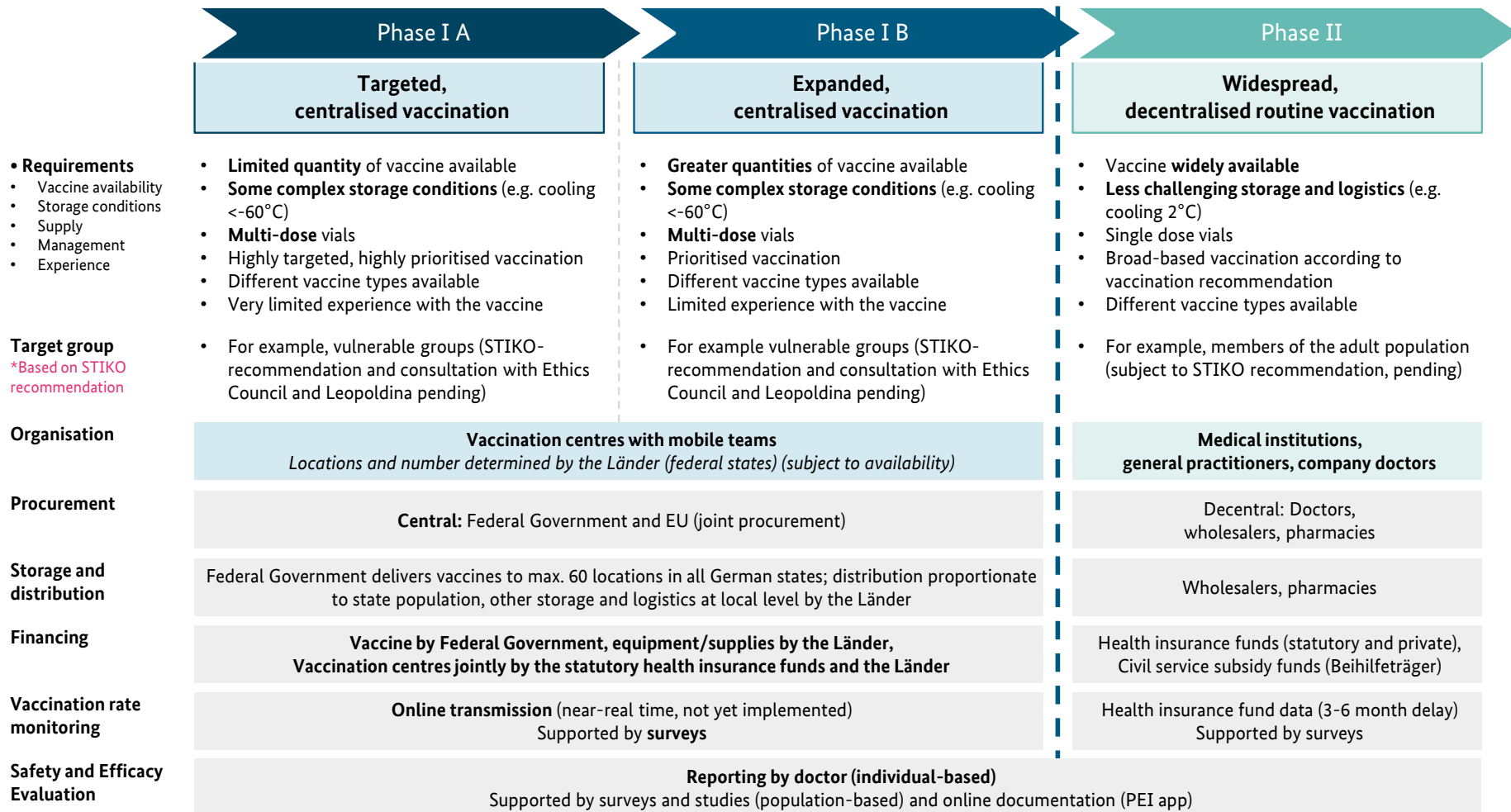
RKI is represented in the WHO/Europe Regional Working Group on Covid-19 Vaccination and Deployment and also in the WHO SAGE Working Group on Covid-19 Vaccines. In the ECDC-coordinated EU Network of National Vaccination Commissions, RKI is the lead organisation in a “living systematic review” on the efficacy and safety of the Covid-19 vaccines and thus provides key input to aid decision-making concerning the Covid-19 vaccination strategies in other EU countries.

As a collaboration centre for vaccines and blood products, PEI supports, among others, the WHO, the regulatory authorities in African partner countries, WHO Afro and regulatory bodies of the African Union in establishing structures and procedures to promote the approval and implementation of clinical trials for medicines and vaccines and to establish effective pharmacovigilance in the use of medical products.

- The Federal Government is responsible for cooperation and coordination at international level.
- The authorities that fall within BMG’s remit (RKI and PEI) conduct specific projects for international cooperation, including in relation to the vaccination strategy.



# Covid-19 Pandemic Vaccination – Implementation in 2 Phases



STIKO = Standing Committee on Vaccination at the Robert Koch Institute | Länder = Federal states



Last updated: 06 November 2020 (S.D.)