Guidelines for applicants

First bilateral call for projects on antimicrobial resistance, launched jointly by the French Ministry of Higher Education, Research and Innovation (MESRI) and the German Federal Ministry of Education and Research (BMBF)

Submission Deadline: February 27, 2019; 1 PM (CET)

Address of publication:
http://anr.fr/ANR-FRDE-AMR-2019

Online submission:
https://aap.agencerecherche.fr/_layouts/15/SIM/Pages/SIMNouveauProjet.aspx?idAAP=1337

For further information please contact the Joint Call Secretariat (JCS) at:

ANR
50 Avenue Daumesnil
75012 Paris

Email: FRDE-AMR@anr.fr
Phone: +33 1 78 09 80 22/+33 1 73 54 81 52
BACKGROUND

France and Germany, in a joint effort to strengthen Europe’s preparedness for this century's big challenges and to further develop the European research landscape, reached an agreement on an important international objective this summer, the fight against antimicrobial resistance on a global scale. Both countries have the necessary expertise and resources to tackle AMR through the formation of productive bilateral research collaborations. Hence, the French Ministry of Higher Education, Research and Innovation (MESRI) and the German Federal Ministry of Education and Research (BMBF) have each committed 7 million euros for a new bilateral program on AMR. The French National Research Agency (ANR) and the agency VDI/VDE-IT, which will be managing the program for BMBF, are charged with the launch of two bilateral calls meant to address unmet needs within the AMR field. ANR and VDI/VDE-IT are proud to announce the launch of the program’s first call in December. French and German scientists are invited to set up productive research collaborations, whose outcomes/results could be implemented into current French and German public health policies or products tackling AMR.

The specific aims, eligibility and evaluation criteria of this first joint call are outlined in the call text. Applicants must refer and comply with the specific national regulations of their respective management agency.

This present document briefly explains the management of the call and the submission process.

MANAGEMENT OF THE CALL

Two managing agencies, ANR and VDI/VDE Innovation + Technik GmbH, are jointly responsible for the launch, implementation and monitoring of the call. Based on the scientific recommendations by the peer review panel (PRP), both agencies will decide on which research consortia to fund.

ANR will be the Joint Call Secretariat (JCS), which is the central contact point for applicants and evaluators.

The Peer Review Panel (PRP) consists of internationally recognized scientists from European research institutions, chosen for their scientific and/or technical expertise. The panel is responsible for the scientific evaluation of the proposals as well as for the ranking of all proposals.

REGISTRATION

For all details regarding the registration of your project on our website, please consult the guidelines in Annex 2. The following is the link to the electronic submission site.

https://aap.agencerecherche.fr/_layouts/15/SIM/Pages/SIMNouveauProjet.aspx?idAAP=1337

Either the French or the German coordinator of a research consortium must register the project; the website accepts only one coordinator. All other members have to be added as partners. Only the coordinator who registered the project can add partners and modify all information pertaining to the project, whereas partners will only be able to add their own information (administrative or financial). Please note that the role of the coordinator on the site can be modified at any time.

The electronic submission site will open on December 21, 2019.

PROPOSAL SUBMISSION

There will be a one-stage submission procedure. A joint bilateral proposal document (in English) shall be prepared by the consortium members and must be submitted electronically to the Joint Call Secretariat (JCS) by either the French or the German coordinator, using the link above.
Because the site does not allow the assignment of two coordinators to one project, the second coordinator and all other partners will have access to the site as observer. All consortium members will have to enter their personal information. All data pertaining to the applications will be shared with the partner agency VDI/VDE-IT and with BMBF.

Please use the proposal template (Word format) provided on the site of the publication of the call: http://anr.fr/ANR-FRDE-AMR-2019; no other template will be accepted. The joint proposal must be submitted in an electronic version not later than February 27, 2019 at 1 p.m. CET.

Please note that a signed paper version of your proposal will not be solicited. However, the electronic proposal needs to be signed (electronic signature or a scan of the paper containing the signature will be accepted).

Furthermore, it is highly recommended to register and provide all requested data/information in due time, because the online data entry may be overloaded immediately before the deadline.

**PROPOSAL STRUCTURE**

Please use only the proposal template provided on the site of the publication of the call: http://anr.fr/ANR-FRDE-AMR-2019. The proposal document must respect the format and the length indicated. Proposals exceeding these limitations will be rejected.

The following proposal structure will be required:

**General information on the project proposal; please include the following information in this section:**

- Project acronym
- Project title
- Project duration
- Total requested budget at ANR, at BMBF
- Keywords
- Project abstract (max ½ page)
- Contact details and affiliations of the two (French and German) project coordinators as well as of all the applicants
- Scientific areas

**Project description**

- Background and current state of the art in the field
- Working hypothesis and preliminary results/previous work
- Description of the aims and main work packages
- Detailed work plan (work packages, milestones, deliverables, tasks per applicant)
- Added value of the bilateral collaboration
- Potential impact of results on current clinical practice and public health policies tackling AMR
- Plan for data management and data sharing
- Potential risks associated with the project
- Statement on ethics approval
- Intellectual property rights
- Other research grants related to the present proposal
- Overall and detailed financial plan of the costs/requested budget for each applicant
The section “Project description” of the submission form (points 1a to 12) must not exceed a maximum of 20 pages (Arial 11, single-spaced, margins of 1.5 cm). Please refer to the template for further information on each section, including length specifications.

**Description of the consortium**

- CV of all consortium members
- Letter of intent signed by all consortium members

A CV of all consortium members must be integrated into the submission form (scientific document). A CV of the other contributors, depending on their level of involvement, can also be joined to the scientific document. A joint CV must not exceed 2 pages and must include a list of no more than 5 principal publications. However, it will possible to include a link in order to access CVs that are more detailed and/or a more comprehensive list of publications.

Experts not suited to review a proposal due to conflict of interest (e.g. direct competition) can be named during the submission process.

All applicants must sign a letter of intent, and thus confirm their commitment to the joint project.

**Before submission, please verify that:**
- The proposal falls within the scope of the call
- The proposal fulfils all eligibility criteria
- All consortium members fulfil the national eligibility requirements (Annex 1)

If questions remain, please contact the JCS or the national representative regarding specific national regulations.

**REBUTTAL**

Please note that project coordinators will be provided with the opportunity to respond to the reviewers’ comments. This step allows applicants to comment on factual errors or misunderstandings committed by the reviewers. Issues not related to the reviewers’ comments may not be addressed. Applicants will have one week (April 30 – May 7, 2019) for this optional step.

**PROJECT START AND CONSORTIUM AGREEMENT**

Consortium members of projects selected for funding must fix a common project start date, which must appear in the Consortium Agreement.

It will be the responsibility of the research consortium coordinators to draw up a Consortium Agreement (CA) in order to manage the delivery of the project activities, finances, intellectual property rights (IPR) and to avoid disputes which might be detrimental to the completion of the project. Please refer to the specific national requirements regarding the submission of the signed CA to the two funding agencies.

The following subjects (as a minimum) should be addressed in the CA:

- purpose of and definitions used in the CA
- names of organisations involved
- common start date of the research project
- organisation and management of the project
role and responsibilities of the research consortium coordinator and the research partners:
- person in charge, their obligations and key tasks, conditions for their change
- deliverables (transnational reports and if relevant requirements for national reports where coordination is required)
- resources and funding
- confidentiality and publishing
- Intellectual Property Rights (how this issue will be handled between research partners)
- decision making within the consortium
- handling of internal disputes
- the liabilities of the research partners towards one another (including the handling of default of contract)

ANNEX 1: SPECIFIC FUNDING RULES OF THE TWO MANAGING ORGANISATIONS

<table>
<thead>
<tr>
<th>Funding Organisation</th>
<th>Agence Nationale de la Recherche (ANR); <a href="http://www.agence-nationale-recherche.fr">http://www.agence-nationale-recherche.fr</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial funding pre-commitment</td>
<td>Approx. 3.500.000 € (French funding) Anticipated number of funded joint projects: 6-8</td>
</tr>
<tr>
<td>National Contact Point</td>
<td>Dr. Ingrid Pfeifer and Dr. Ana Navarette; Phone : +33 (0)1 78 09 80 22 /+33 (0)1 73 54 81 52 E-Mail: <a href="mailto:FRDE-AMR@anr.fr">FRDE-AMR@anr.fr</a>; Health &amp; Biology Department; Agence Nationale de la Recherche –ANR; 50, avenue Daumesnil - 75012 Paris, France</td>
</tr>
<tr>
<td>Eligible institutions</td>
<td>Eligible institutions:</td>
</tr>
<tr>
<td></td>
<td>- Public Research Organization such as EPST, EPIC, universities, university hospitals, public research institutes (max. rate of support: 100% of marginal costs).</td>
</tr>
<tr>
<td></td>
<td>- Enterprises: large &amp; SMEs (max. rate of support: 45% of eligible costs for SMEs &amp; 30% for larger companies).</td>
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<tr>
<td></td>
<td>- Most of the foundation of Public utility, actor of the research (50% of eligible costs)</td>
</tr>
<tr>
<td></td>
<td>- Private health establishments of public interest (ESPIC) (max. rate of support: 100% of marginal costs)</td>
</tr>
<tr>
<td></td>
<td>Please see the financial regulation on the ANR web site for additional information Please refer to ANR’s financial regulations (“Règlement financier ANR”) for full details at: <a href="http://www.agence-nationale-recherche.fr/RF">http://www.agence-nationale-recherche.fr/RF</a></td>
</tr>
<tr>
<td>Additional eligibility criteria</td>
<td>- ANR will not allow double funding and will not finance projects or parts of projects that have been funded through other calls.</td>
</tr>
<tr>
<td>Eligible costs</td>
<td>Personnel costs for temporary contracts; Instruments, material and scientific consumable cost; travel; and sub-contracting, if necessary to carry out the</td>
</tr>
</tbody>
</table>
proposed activities (sub-contracting costs of max 50% of total eligible costs per principal investigator).
Please note that at ANR, indirect costs (i.e. overheads) means « Frais généraux (additionnels et autres frais d’exploitation)”, section 3.1.1.e of the financial regulation of ANR, and 8% of the total eligible costs must be applied if the applicant belongs to a public research organisation, whereas 68% of the total personnel costs and 7% of other costs will be applied if the PI belongs to another category.
ANR has a maximum funding per applicant for this call: each applicant can be funded with a maximum amount of 250 000 €. There is equally a minimum amount per applicant: 15 000 €.

Further guidance

Please see online the specific annexe document for research groups applying to this call for proposals for funding in France, available via a link on the site of the publication of the call on the ANR site:
http://anr.fr/ANR-FRDE-AMR-2019

<table>
<thead>
<tr>
<th>Funding Organisation</th>
<th>Federal Ministry of Education and Research (BMBF)</th>
<th><a href="https://www.bmbf.de/">https://www.bmbf.de/</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial funding pre-commitment</td>
<td>Approx. 3.500.000 € (German funding)</td>
<td>Anticipated number of funded joint projects: 6-8</td>
</tr>
<tr>
<td>National Contact Point</td>
<td>Dr. Karsten Rapsch</td>
<td>Communication Systems, Human-Machine-Interaction, Health</td>
</tr>
<tr>
<td></td>
<td>VDI/VDE Innovation + Technik GmbH</td>
<td>Steinplatz 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10623 Berlin</td>
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<td></td>
<td></td>
<td>Germany</td>
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<tr>
<td></td>
<td></td>
<td>Phone: +49 (0) 30 310078-498</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mail: <a href="mailto:Karsten.Rapsch@vdivde-it.de">Karsten.Rapsch@vdivde-it.de</a></td>
</tr>
<tr>
<td>Eligible institutions</td>
<td>Eligible institutions:</td>
<td>Public and private universities and universities of applied science, non-university research institutions (FhG, MPG, HGF, WGL), university hospitals and companies in the industrial sector with R &amp; D capacity in Germany</td>
</tr>
<tr>
<td>Additional eligibility criteria</td>
<td>The required expertise and infrastructure for the realization of the project is required. Business enterprises can only be promoted if the financial standing of the company is guaranteed for the project duration.</td>
<td></td>
</tr>
<tr>
<td>Eligible costs</td>
<td>All costs related to the project, which are not covered by basic financing, are eligible. This includes personal costs, consumables, travel costs, in exceptional cases</td>
<td></td>
</tr>
</tbody>
</table>
investments, publication costs, subcontracts and other expenses. The respective funding rates are linked to national regulation, please refer to the national call text.

| Further guidance | Further information and national regulations are available in the German call text. Additionally, German applicants are advised to refer to the German call text and to contact their respective national contact point. [https://www.gesundheitsforschung-bmbf.de/de/8364.php](https://www.gesundheitsforschung-bmbf.de/de/8364.php) |
ANNEX 2: GUIDELINES FOR THE SUBMISSION WEBSITE

Access the website to create your project:

One of the two project coordinators has to be the coordinator on the site.

Go to the link: https://aap.agencerecherche.fr/_layouts/15/SIM/Pages/SIMNouveauProjet.aspx?idAAP=1337

Create your account

You will receive immediately a mail from our website (from: simnoreply@agencerecherche.fr Object: Creation d'un nouveau project / Creation of a new proposal) the mail could arrive to your spam, so if you do not receive it do not hesitate to check your spam mails.
Access our website

You can modify the language to English.

Be sure that the role that appears is “Project coordinator”
Create your project

Please fill in the informations below to create your project. These will remain modifiable until the close of the call for projects.

Identity of the project

- Project acronym: CLOX
- Project French title: Les patates ne poussent plus
- Project English title: Not set
- R & D category: Sélectionnez une catégorie R&D

Identity of the coordinator of the project

Principal investigator/Scientific manager of the partner

- All boxes with asterisk are mandatory

Please save frequently to avoid losing your work.

You will be the coordinator of the project. As coordinator you must add in this page basic information of the project: project Name (Acronym); title in French and English, and your name and nationality.

After saving this information, a new window will open with different tabs. (See the image below)
You have to go to each tab and add the requested information.

Further information concerning the project can be added in the tab “identity of the project”
1. Identity of the project:

The name of the project (Acronym); the title in English and French, duration of the project should be informed in this section.

Also, you should provide one or more of the keywords associated with the aim the call for your project.

Please save frequently to avoid losing your work.
2. Partnerships and tasks:

How to add a research partner:

Click on the icon to create your research partner, a window opens

You must click on the icon “select a Principal investigator”

Another window opens. Add the mail, name or last name of the person to see if this information are already in the database….
If the person is in our data base you can assign the person to the project

After you can add information pertaining to the organization of this partner. (Country, Category (Public or Private Organization) Name of the organization…please safe this information. The partner will receive a mail from the site inviting him/her to create an account. The partner can then directly enter his/her information.

You can choose the agency according to your country (VDI/VDE-IT/ or ANR)

However if the partner will belong to one of this two countries but will joint with his own fund you can modified and choose with “With own funds”.

If the partner do not belong to any of these countries only the choice “with own funds” will be only possible.
If the person is not in our data base

If the person is not in our base, you can create a new person. Further, assign him/her to the project and create the person (to create the partner add the mail of the partner)
After a new window opens

Click hear to confirm, it is not necessary to enter all the required information at this point. The partner can enter this information directly.

Now you can assign the partner to the project.
Each partner can now add his/her administrative and financial information directly online. To do so go to step 3 Partners/Organization files

Modification of a partner:

- Click on the dots to modify information on the partner
- Click on the dots to delete a partner
3. Partners/Organization files (to be filled by each partner directly from his or her account)

All partners will receive a mail from our site inviting him to create a password and access the website.

Partners can add their own information (administrative, financial) to the website.

- Add the administrative data
- Fill information concerning the partner
- For Public Organization you should choose: [Nouvelle catégorie 1 Pub]
- For Private (Entreprises) you should choose: Nouvelle Catégorie 2 (Entrep)]
3. Partners/Organization files

- Add the administrative data
- Information concerning the organization of the partner
- Add the scientific team

**Principal Investigator/Scientific manager**

- Civilty of the scientific manager
- First name of the scientific manager
- Last name of the scientific manager
- Birth date
- Title of the scientific manager
- ORCID Number
- Phone of the scientific manager
- Mobile phone of the scientific manager
- Mail of the scientific manager

**Scientific team partner's member**

- None

*Note that users with only the scientific team member role do not have an account to log into the application.*

**Add new member**

**Delete selected member**

**Other**

- By submitting this proposal to ANR, I undertake moral commitment to provide scientific evaluations of proposals submitted in other ANR calls for which I could be requested.

- Key words of your area of expertise (key words must be separated by a semicolon)

**Save**
**Cancel**
### 3. Partners/Organization files

**For French public partners**

Please select the partner/organisation in the table(s) above and then update its administrative and financial data below.

<table>
<thead>
<tr>
<th>Administrative data</th>
<th>Financial data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Partnership type</strong></td>
<td><strong>Estimated costs</strong></td>
</tr>
<tr>
<td><strong>RNSR Code</strong></td>
<td><strong>Type of Unit</strong></td>
</tr>
<tr>
<td><strong>Partner country</strong></td>
<td><strong>Unit number</strong></td>
</tr>
<tr>
<td><strong>Partner category</strong></td>
<td><strong>Calculation basis for grant marginal or full cost when the organization is public or private respectively</strong></td>
</tr>
</tbody>
</table>

- **Choose [Nouvelle catégorie 1 Pub]**
- **French RNSR Code**
- **Type of Unit and Unit number**
- **The calculation basis for the grant marginal or full cost when the organization is public or private respectively**

To optimize the entry of your partner form, please enter your French RNSR code then click on "Find information associated with the French RNSR code".
3. Partners/Organization files

Add the administrative data

For French public partners

Add mandatory information concerning the organization and personal information of the principal investigator of the partnership. (*)
3. Partners/Organization files

Add the administrative data

For French public partners

Add mandatory information concerning the address of the place where the scientific work will be done, concerning the legal representative and the person in charge of the follow up of the project if financed.

Click on the “+” so you can see the information to requested.
3. Partners/Organization files

Add the administrative data

For French private partners (Entreprises) (Partner Category: Nouvelle Catégorie 2 (Entrep))

In order to be an eligible partner for the funding as an enterprise, you have to test the financial health of your business for the ANR by clicking in this icon.

Calculation basis for grant base: Full cost
3. Partners/Organization files

For French private partners (Entreprises)

A new window opens so you can download a file that will invite you to check the financial health of your company.

Add the administrative data.
3. Partners/Organization files

For German partners (From either Public or Private Organizations)

Click on the folder Financial Data on the "Partners/Organization files folder.

Add the full cost of your part of the project and the amount requested for funding. This value can be equal.
3. Partners/Organization files

Add the Financial data

For French partners

Add your financial data in the format requested by ANR in order to handle the follow up of the project, if financed.

The financial information from the French side should be filled according to the ANR rules. (for further information: see: http://www.agence-nationale-recherche.fr/financer-votre-projet/reglement-financier/)
4. Scientific abstract

Add the scientific abstract in English and French, the overall objectives, scientific and technical barriers; the work program and the scientific, technological and economic benefits
5. Upload the scientific document

Add the scientific document in a PDF format and respecting the number, the pages suggested in the template of the call.
6. Peer reviewers

You can add if you desire a potential conflicted reviewer so the agencies do not contact him to evaluate your project due to conflicts.

7. Submission of the project

Once you consider the file complete, you may leave the site (all data will have automatically been submitted). Modifications are possible until the submission deadline, February 27, 2019 at 1 PM (CET). You will receive a mail confirming receipt and the state of your application only after this date.
ANNEX 3 – TECHNOLOGY READINESS LEVELS (TRLs)

All topics listed in this call text (except topic III) refer to particular TRLs. Please verify that the TRLs of your project correspond to the TRLs specified in the call topic to which the project relates. Please below find the individual TRL descriptions.

Source: FDA

TRL 1 Review of Scientific Knowledge Base
Active monitoring of scientific knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies.

TRL 2 Development of Hypotheses and Experimental Designs
Scientific “paper studies” to generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Focus on practical applications based on basic principles observed. Use of computer simulation or other virtual platforms to test hypotheses.

TRL 3 Target/Candidate Identification and Characterization of Preliminary Candidate(s)
Begin research, data collection, and analysis in order to test hypothesis. Explore alternative concepts, identify and evaluate critical technologies and components, and begin characterization of candidate(s). Preliminary efficacy demonstrated in vivo.

- 3A Identify target and/or candidate.
- 3B Demonstrate in vitro activity of candidate(s) to counteract the effects of the threat agent.
- 3C Generate preliminary in vivo proof-of-concept efficacy data (non-GLP (Good Laboratory Practice)).

TRL 4 Candidate Optimization and Non-GLP In Vivo Demonstration of Activity and Efficacy
Integration of critical technologies for candidate development. Initiation of animal model development. Non-GLP in vivo toxicity and efficacy demonstration in accordance with the product's intended use. Initiation of experiments to identify markers, correlates of protection, assays, and endpoints for further non-clinical and clinical studies.

- Animal Models: Initiate development of appropriate and relevant animal model(s) for the desired indications.
- Assays: Initiate development of appropriate and relevant assays and associated reagents for the desired indications.
- Manufacturing: Manufacture laboratory-scale (i.e. non-GMP (Good Manufacturing Practice)) quantities of bulk product and proposed formulated product.
- 4A Demonstrate non-GLP in vivo activity and potential for efficacy consistent with the product's intended use (i.e. dose, schedule, duration, route of administration, and route of threat agent challenge).
- 4B Conduct initial non-GLP toxicity studies and determine pharmacodynamics and pharmacokinetics and/or immune response in appropriate animal models (as applicable).
- 4C Initiate experiments to determine assays, parameters, surrogate markers, correlates of protection, and endpoints to be used during non-clinical and clinical studies to further evaluate and characterize candidate(s).

TRL 5 Advanced Characterization of Candidate and Initiation of GMP Process Development
Continue non-GLP in vivo studies, and animal model and assay development. Establish draft Target Product Profiles. Develop a scalable and reproducible manufacturing process amenable to GMP.

- Animal Models: Continue development of animal models for efficacy and dose-ranging studies.
- Assays: Initiate development of in-process assays and analytical methods for product characterization and release, including assessments of potency, purity, identity, strength, sterility, and quality as appropriate.
- Manufacturing: Initiate process development for small-scale manufacturing amenable to GMP.
- Target Product Profile: Draft preliminary Target Product Profile. Questions of shelf life, storage conditions, and packaging should be considered to ensure that anticipated use of the product is consistent with the intended use for which approval will be sought from FDA.
- 5A Demonstrate acceptable Absorption, Distribution, Metabolism and Elimination characteristics and/or immune responses in non-GLP animal studies as necessary for IND filing.
- 5B Continue establishing correlates of protection, endpoints, and/or surrogate markers for efficacy for use in future GLP studies in animal models. Identify minimally effective dose to facilitate determination of “humanized” dose once clinical data are obtained.

TRL 6 GMP Pilot Lot Production, IND Submission, and Phase 1 Clinical Trial(s)
Manufacture GMP-compliant pilot lots. Prepare and submit Investigational New Drug (IND) package to FDA and conduct Phase 1 clinical trial(s) to determine the safety and pharmacokinetics of the clinical test article.

- **Animal Models:** Continue animal model development via toxicology, pharmacology, and immunogenicity studies.
- **Assays:** Qualify assays for manufacturing quality control and immunogenicity, if applicable.
- **Manufacturing:** Manufacture, release and conduct stability testing of GMP-compliant bulk and formulated product in support of the IND and clinical trial(s).
- **Target Product Profile:** Update Target Product Profile as appropriate.
- **6A** Conduct GLP non-clinical studies for toxicology, pharmacology, and immunogenicity as appropriate.
- **6B** Prepare and submit full IND package to FDA to support initial clinical trial(s).
- **6C** Complete Phase 1 clinical trial(s) that establish an initial safety, pharmacokinetics and immunogenicity assessment as appropriate.

**TRL 7 Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trial(s)**

Scale-up and initiate validation of GMP manufacturing process. Conduct animal efficacy studies as appropriate. Conduct Phase 2 clinical trial(s).

- **Animal Models:** Refine animal model development in preparation for pivotal GLP animal efficacy studies.
- **Assays:** Validate assays for manufacturing quality control and immunogenicity if applicable.
- **Manufacturing:** Scale-up and validate GMP manufacturing process at a scale compatible with USG requirements. Begin stability studies of the GMP product in a formulation, dosage form, and container consistent with Target Product Profile. Initiate manufacturing process validation and consistency lot production.
- **Target Product Profile:** Update Target Product Profile as appropriate.
- **7A** Conduct GLP animal efficacy studies as appropriate for the product at this stage.
- **7B** Complete expanded clinical safety trials as appropriate for the product (e.g., Phase 2).

**TRL 8 Completion of GMP Validation and Consistency Lot Manufacturing, Pivotal Animal Efficacy Studies or Clinical Trials 3, and FDA Approval or Licensure**

Finalize GMP manufacturing process. Complete pivotal animal efficacy studies or clinical trials (e.g., Phase 3), and/or expanded clinical safety trials as appropriate. Prepare and submit NDA/BLA.

- **Manufacturing:** Complete validation and manufacturing of consistency lots at a scale compatible with USG requirements. Complete stability studies in support of label expiry dating.
- **Target Product Profile:** Finalize Target Product Profile in preparation for FDA approval.
- **8A** Complete pivotal GLP animal efficacy studies or pivotal clinical trials (e.g., Phase 3), and any additional expanded clinical safety trials as appropriate for the product.3
- **8B** Prepare and submit New Drug Application (NDA) or Biologics Licensing Application (BLA) to the FDA.
- **8C** Obtain FDA approval or licensure.

**TRL 9 Post-Licensure and Post-Approval Activities**

- **9A** Commence post-licensure/post-approval and Phase 4 studies (post-marketing commitments), such as safety surveillance, studies to support use in special populations, and clinical trials to confirm safety and efficacy as feasible and appropriate.
- **9B** Maintain manufacturing capability as appropriate.

Source: FDA