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Introduction to the pilot projects and introduction to the exercise

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What is a pilot project?

" (…) pilot studies should assess the feasibility/acceptability of the approach to be used in the larger study, and **answer the "Can I do this?" question**. "

"Also commonly know as "feasibility" or "vanguard" studies, they are designed to **assess the safety of treatment or interventions**; to **assess recruitment potential**; to **assess the feasibility of international collaboration or coordination** for multicentre trials; to **increase clinical experience** with the study medication or intervention for the phase III trials. "

" A pilot study is performed either as an external pilot study **independent of the main study** or as an internal pilot study **included in the research design of the main study**. "

National Institutes of Health. Pilot Studies: Common Uses and Misuses. https://www.nccih.nih.gov/grants/pilot-studies-common-uses-and-misuses. Accessed 07/03/2024

In J. Introduction of a pilot study. Korean J Anesthesiol. 2017 Dec;70(6):601-605. doi: 10.4097/kjae.2017.70.6.601. Epub 2017 Nov 14. PMID: 29225742.

Thabane L, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010 Jan 6;10:1. doi: 10.1186/1471-2288-10-1. PMID: 20053272.

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What are the goals of a pilot project?

Classically: a precursor to guide the design of a larger study

For us → a “small” study with the goals of:

- Answer a question
- Guide informed action
- Identify opportunities for capacity building

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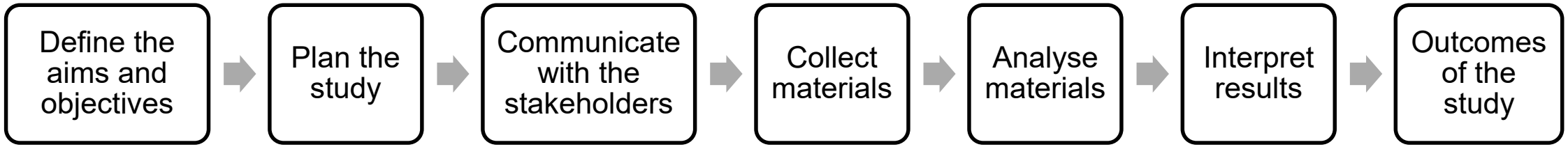
What are the main steps of a pilot project?



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Exercise on pilot projects

Part 1 (in groups)

Identify one **important gap in your national surveillance - one gap per country**

Examples of gaps:

- Unsure of how many cases of *Campylobacter* occur per year
- Unsure of the distribution of circulating *Salmonella* serovars
- Unsure of which resistance profiles have emerged in the country in the past 5 years
- Unsure of which relevant AMR genes circulate in the country
- Unsure of the burden of AMR in intensive care units
- Unsure of number of cases in long-term care facilities

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Exercise on pilot projects

Part 2 (in groups)

Design a **pilot project that would help solve the gap** in your national suveillance - **one project per country**

Example:

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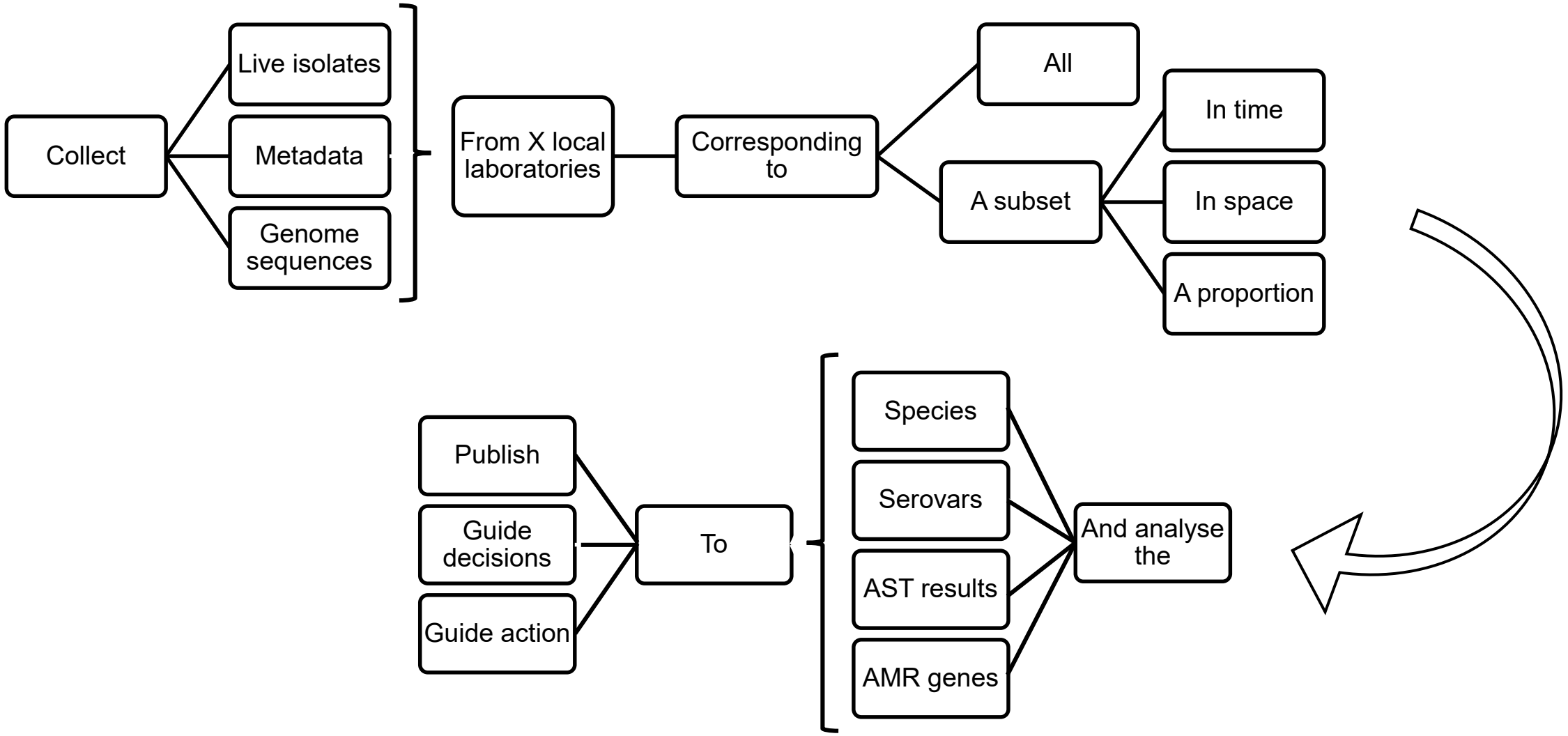
Exercise on pilot projects



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Exercise on pilot projects

Part 2 (in groups) – cont.

Try to **design a plan for those pilot projects**

If there's no time for all projects, choose one in the group

Follow the template – you can make relevant changes

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Exercise on pilot projects

1. Objective and scope of the pilot study

Describe the objective, e.g. a capacity building goal, improvement of national surveillance, etc.

What problem am I trying to solve?

What is the overall aim?

2. Collection of isolates for the pilot study

Specify the number of isolates that will be included in the pilot study.

How many isolates I would like to test?

What is realistic in terms of timeline and budget?

3. Inclusion/exclusion criteria

Define the inclusion and/or exclusion criteria of the pilot study, e.g. the pathogens and phenotypes of interest, the geographical origin (local laboratories, hospitals or other sites), the source (specific patients or wards, etc.) and time period.

What types of isolates do I need?

What is the geographical/population coverage?

What are the inclusion/exclusion criteria?

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Exercise on pilot projects

4. Communication

Define how you are going to communicate with the local laboratories or other stakeholders that will provide the materials.

What plans for communicating with participants?

How to make them interested in the project?

What plans to receive material and/or data from them?

5. Collection of patient data

Specify which patient data (or metadata) that you plan to include in the pilot study, e.g. age, gender, in/out patient, hospital location and sector, name/type of ward, etc.

What information will support my analysis and my results?

6. Collection of microbiology testing data

Specify collection date, location of pathogen (in organ or system), occurrence of infection or colonisation.

What (preliminary?) information can I collect from the participants?

How to harmonize this information?

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Exercise on pilot projects

7. Collection of epidemiology data

Specify data relevant to the epidemiological investigations of the pilot study, including patient location, hospitalisation periods, hospital transfers, travel history, etc.

What information can I collect from the participants?

How to harmonize this information?

8. Plans for analysis

Specify the laboratory testing, e.g. species identification, phenotypic antimicrobial susceptibility testing, PCR, WGS, etc.

What do I want to know?

What equipment do I have?

Is this feasible in my laboratory (time, personnel, etc.)

9. Plans for interpretation of results

Specify your plans for interpreting the results collected above, e.g. interpreting AST according to EUCAST guidelines, grouping isolates based on genes detected through PCR, clustering isolates based on WGS results.

How do I answer my main questions?

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Exercise on pilot projects

10. Timeline of the pilot study

Describe your timeline, including details for the steps of collecting isolates and data, analysis and interpretation.

Should be realistic.

11. Outcomes of the pilot study

Describe the potential outcomes of the pilot study, e.g. updating national guidelines to include a new phenotype or gene of interest, or a report with WGS-based findings that will be discussed with national stakeholders to promote the implementation of the technology at the NRL.

What are the results going to be used for?

What are the “next-steps”?

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Exercise on pilot projects

The ideas must be relevant for the **specific situation in your country**.

The members of the groups can (and should) have different ideas.

The members of the groups don’t need to choose the same project to design in detail, but should collaborate with each other to help design their respective projects.

These ideas can be implemented in real life and you can use the tailored support from your FWD AMR-RefLabCap team to further develop them during the priority country meetings.

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Exercise on pilot projects - Groups

1	Ana Gverić Grginić	Croatia **
	Ivana Ferencak	Croatia **
	Svetlana Mikovic Dramlic	Serbia
	Jana Pešić Stanković	Serbia
	Laura Villa	Italy
2	Oksana Savicka	Latvia **
	Reinis Vangravs	Latvia **
	Olga Burduniuc	Moldova
	Livia Tapu	Moldova
3	Maria Pavlova	Bulgaria **
	Rositsa Stoyanova	Bulgaria **
	Barbora Zapletalová	Czechia
	Lucia Mališová	Czechia

4	Jelena Razmuk	Lithuania **
	Jekaterina Sinotova	Lithuania **
	Lina Thebo	Sweden
	Verica Mioč	Slovenia
5	Liisa Lilje	Estonia **
	Kairi Tõnsau	Estonia **
	Anne Carroll	Ireland
	Silvia Herrera León	Spain
6	Alica Brodova	Slovakia **
	Codruta-Romanita Usein	Romania
	Daniela Cristea	Romania
	Mag Tünde	Hungary

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