



How to develop a research protocol

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Objectives of this session

Able to:

- Understand the different steps of a research protocol and its importance.
- Develop a research protocol of their topic of interest.



What is research?

- Research is the systematic collection, analysis and interpretation of data to answer a certain question or solve a problem



Key Points of Your Proposal

What is your research question ?

Why is your study important ?

How are you going to do it ?

Protocol

- The reason for having a study plan or protocol is efficiency in carrying out the study.
- Able to do the intended study quickly, easily and ethically.
- Here is a example of protocol outlines

Study protocol outline

Element	Purpose
1. Research questions	What questions will the study address?
2. Significance (background)	Why are these questions important?
3. Design Time frame Epidemiologic approach	How is the study structured?
4. Subjects Selection criteria Sampling design	Who are the subjects and how will they be selected?
5. Variables Predictor variables Confounding variables Outcome variables	What measurements will be made?
6. Statistical issues Hypotheses Sample size Analytic approach	How large is the study and how will it be analyzed?

the process of research in familiar terms:

■ **Anatomy of research** (what it's made of)

- • **Research question**
- • **Significance**
- • **Design**
- • **Subjects**
- – **Population**
- – **Sample size**
- • **Variables**
- – **Predictor**
- – **Outcome**

■ **Physiology of research** (how it works)

- **Using measurements in a sample to draw inferences about phenomena in a population**



Why a protocol?

- To clarify the research question
- To compile existing knowledge
- To formulate a hypothesis and objectives
- To decide about a study design
- To clarify ethical considerations
- To apply for funding
- To have a guideline and tool for the research team



How to judge a good protocol?

- Is it adequate to answer the research question(s), and achieve the study objective?
- Is it feasible in the particular set-up for the study?
- Does it provide enough detail (methodology) that can allow another investigator to do the study and arrive at comparable conclusions?

Title of a research project

- Accurate, short, concise
- Descriptive: should make the main objective clear, should mention the target population
- Key words: should contain key words for referencing
 - i.e. „TB in HIV – infected children“
 - Better: „Incidence of TB in HIV- infected children in South Africa during 2017-2018“



Project summary

- Concise, one page (about 300 words)
- Stands on its own – no reference to protocol content
- Summarizes central elements (rationale, methodology, populations, time frame, expected outcomes)



Statement of the problem

- Why ...is the research needed?
- What ...is the relevance of the results?

Logical flow of statements:

Magnitude, frequency, and distribution: Affected geographical areas and population groups. Ethnic and gender considerations.

Probable causes of the problem: What is the current knowledge of the problem and its causes? Is there consensus? Is there controversy? Is there conclusive evidence?

Possible solutions: In what ways have solutions to the problem been attempted? What has been proposed? What are the results?

Unanswered questions: What remains to be answered? What areas have not been possible to understand, determine, verify, or test?



Literature review

- Prevents duplication of work, which has been done
- Clarifies, what others have found addressing the problem
- Familiarizes with potential methodologies and methodological errors
- Should convince, that the research is needed!



Justification of research

Should be a convincing statement for the need to do this research

- How does the research relate to the priorities of the region and the country?
- What knowledge and information will be obtained?
- What is the ultimate purpose that the knowledge obtained from the study will serve?
- How will the results be used, and who will be the beneficiaries?



RESEARCH QUESTION

IT SHOULD BE A SINGLE SENTENCE IN THE FORM OF A QUESTION.

IT SHOULD BE CLEAR UNAMBIGUOUS AND SPECIFIC



RESEARCH QUESTION

- IS DRUG “A” BETTER THAN DRUG “B” IN THE MANAGEMENT OF HEPATIC FAILURE IN PATIENTS WITH CIRROSIS?
- IS ALCOHOLISM RELATED TO THE DEVELOPMENT OF CIRROSIS LIVER?



Research objectives

Define a **GENERAL OBJECTIVE** and derive **SPECIFIC OBJECTIVES**

The formulation of objectives will help to:

- Focus the study (narrowing it down to essentials)
- Avoid the collection of data which are not strictly necessary for understanding and solving the problem you have identified
- Organize the study in clearly defined parts or phases



Research objectives

Objectives should be:

- Logical and coherent
- Feasible
- Realistic, considering local conditions
- Defined in operational terms that can be measured
- Phrased to clearly meet the purpose of the study (relevant)

Objectives should be stated in **action** verbs that illustrate their purpose:

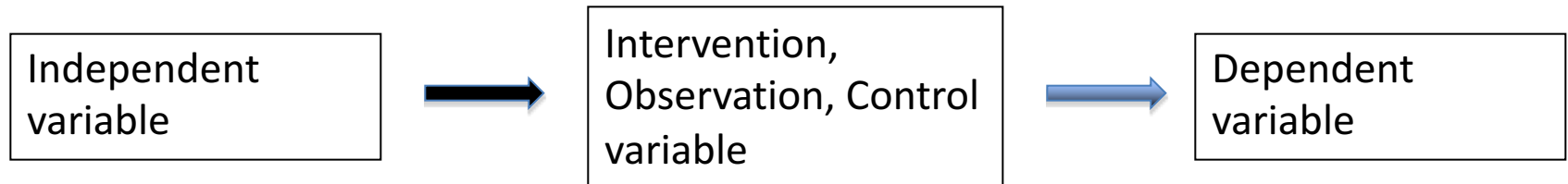
i.e. “To determine..., To compare..., To verify..., To calculate..., To reduce..., To describe..., etc.



■ Objectives –examples

- (1) To study whether SNP markers are associated with obesity and hypertension phenotypes.
- (2) To assess the general population knowledge & attitude towards Organ donation
- (3) To identify the risk factors for Type-II diabetes

Research hypothesis



- Describes the relationship between **INDEPENDENT** variables (risk factors, predisposing factors) and **DEPENDENT** variables (outcome)
- Determines the type of data to be collected and the type of analysis to be conducted



■ Hypothesis-example

- We hypothesize that standard care plus new intervention (additional drug) will be superior (by 25%) to standard care alone in reducing CVD mortality among patients with preexisting heart disease.
- We hypothesize that prophylaxis with inhaled drug A will be more effective to oral preparation of drug B in preventing acute exacerbation of reactive airway disease.
- We hypothesize that low birth weight is an independent risk factor for type II diabetes.



Methodology

Important aspect of the protocol

- Assures, that the hypothesis will be proved or disproved, using the right tools
- Presents a detailed strategy, how the objectives are achieved

Consider

- operational definitions
- study design
- definition of variables
- sample size
- ethical aspects



Methodology

Study design

Interventional study

Clinical trial

Observational study

Cohort study

Cross-sectional study

Case – control study

Ecological study

Methodology

Definition of variables

Conceptual definition of variable	Operational definition i.e., indicator	Scale of measurement
Age	Age at last birthday	Continuous: in months
Family size	Number of family members	Discrete
Use of clinic	Number of visits to clinic	Discrete
Haemoglobin	Haemoglobin concentration in capillary blood, measured by haemoglobinometer	Continuous: e.g., grams per 100 ml., rounded off to nearest gram
Nutritional status	Weight in relation to age compared to a standard growth curve	Ordinal: e.g., 1. well nourished = >80% of standard 2. moderately malnourished = 60% to 80% of standard 3. severely malnourished = <60% of standard
Patient's satisfaction	Response to a specific question about his/her satisfaction with services obtained, put to patients on discharge	Ordinal: e.g., 1. very satisfied 2. somewhat satisfied 3. somewhat dissatisfied 4. very dissatisfied
Immunisation coverage	Percentage of children immunised in a particular age group	Continuous: e.g., percentages; or ordinal, e.g., • high > 80% • medium 60% - 80% • low < 60%
Religion	As reported by informants	Nominal: Christian, Moslem, Hindu, Buddhist, etc.
Main source of carbohydrate in the diet	Main type of staple food eaten	Nominal: e.g., maize, millet, rice, cassava, etc.



Methodology

Measurement of observations

- Describe how, when and where the observations are made? Describe instruments used!
 - Questionnaire (attach to the protocol)
 - Type of interview (describe structure of the interview)
 - Laboratory test (refer to literature or personal knowledge if established test, or describe in detail, if not established)
 - Clinical examinations (describe gadget/procedure)
Describe all instruments or refer to literature if tools are established.
(for intervention studies or drug trials refer to specific literature/regulations)



Methodology

Subjects/ participants

Depending on the type of study, answer the following questions:

- What are the criteria for inclusion or selection?
- What are the criteria for exclusion?
- In intervention studies, how will subjects be allocated to index and comparison groups (Randomization procedure)?
- What are the criteria for discontinuation?



Methodology

Sample size

- Sample size calculation is recommended for economical and ethical reasons
- Simple statistical packages in the internet
- Level of error, power and expected impact of exposure on outcome have to be set



Ethical considerations

Informed consent

Outline how, when and where the patient will be consented!

Information form should contain:

- Justification for research
- Responsibilities (Who)
- Outline of study
- Confidentiality (legal framework)
- A separate consent form is required!



Ethical considerations

Ethics checklist

- Should answer potential questions regarding the ethics
- Should discuss pros and cons of research design, selection of subject, measurement and outcome assessment.
- Should discuss the advantages and disadvantages of the subject or communities involved
- Should discuss physical, social and psychological implications of the research
- Should discuss confidentiality



Data management and analysis

Based on objectives consider:

- Coding for variables/ type of variables
- Analysis plan depending on type of variables
- Appropriate Statistical tests
- (Style of presentation i.e. tables, graphs)



References/Bibliography

- Use of standard referencing system:
 - *Harvard style*
 - Name and publication year in text
 - Alphabetical bibliography
 - *Vancouver style*
 - Numbered references
 - Continuous referencing in text
- Make use of software
 - Reference Manager
 - Endnote software

Work plan

Tasks

ACTIVITY	WHO	JAN	FEB	MARCH	APRIL	MAY
Meeting with clinic staff	All Project Staff	█				
Meeting with District Management	All Project Staff	█				
Design Questionnaire	Researcher	█				
Train Field Workers & Pilot Questionnaire	Researcher and Field Workers		█			
Data Collection	Researcher and Field Worker		█	█		
Analysis	Researcher			█	█	
Meeting with Clinic Staff and District Management	All Project Staff				█	
Write up Full Report	Researcher					█
Write article for Update and Policy Brief	Researcher					█
Meeting with Clinic Staff and District Management	All Project Staff					█

Who?

When?

Where?



Budget

The budget should be broken down by:

- **Items**

- Personnel
- Consumables, equipment, supplies, communication, funds for patients, data processing

- **Budget justification**

- Justify the use of each item, considering the workplan of the study



Annexes

- Case Record Forms (CRFs)
- Questionnaires
- Consent form (in required languages)

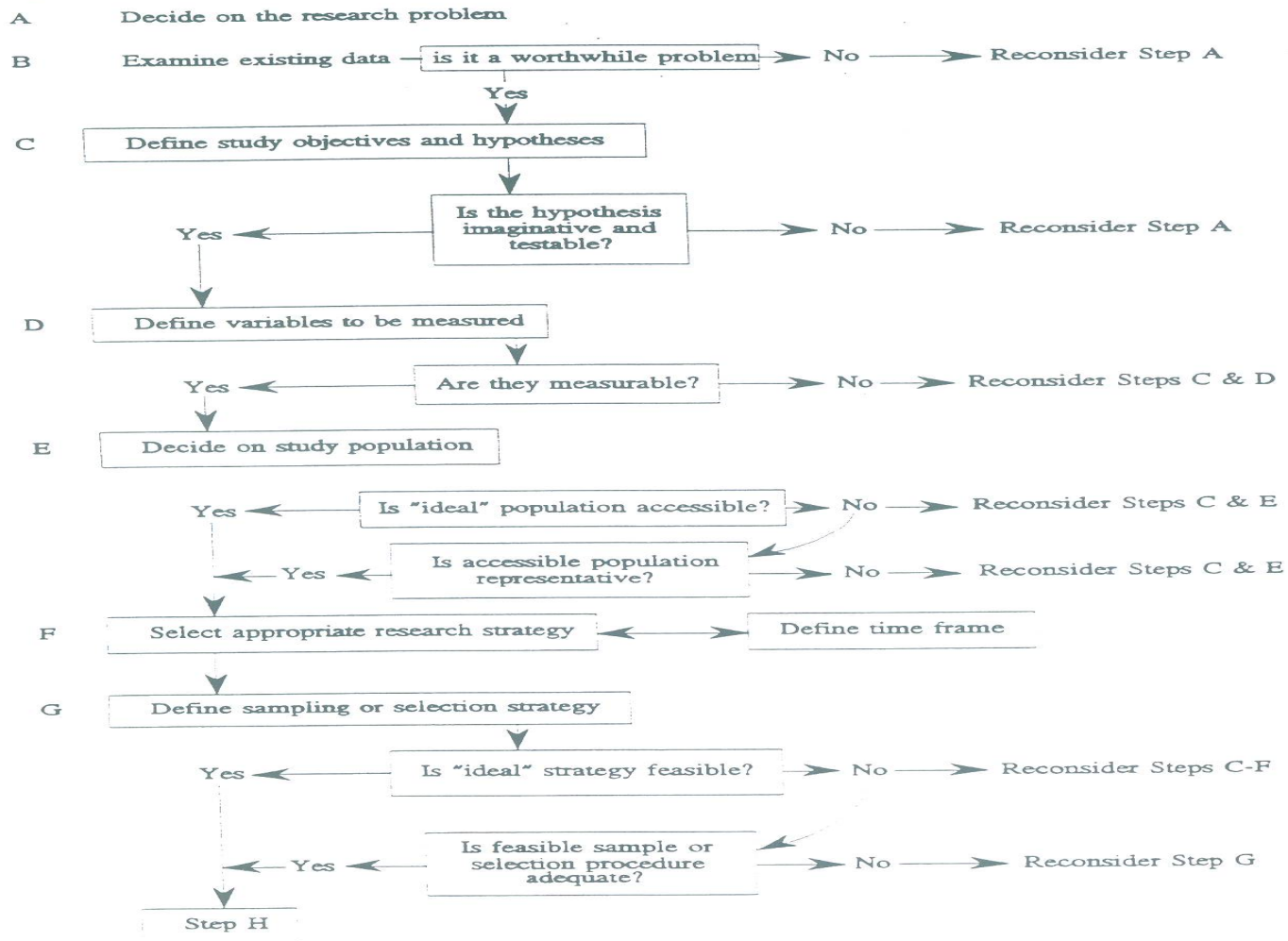


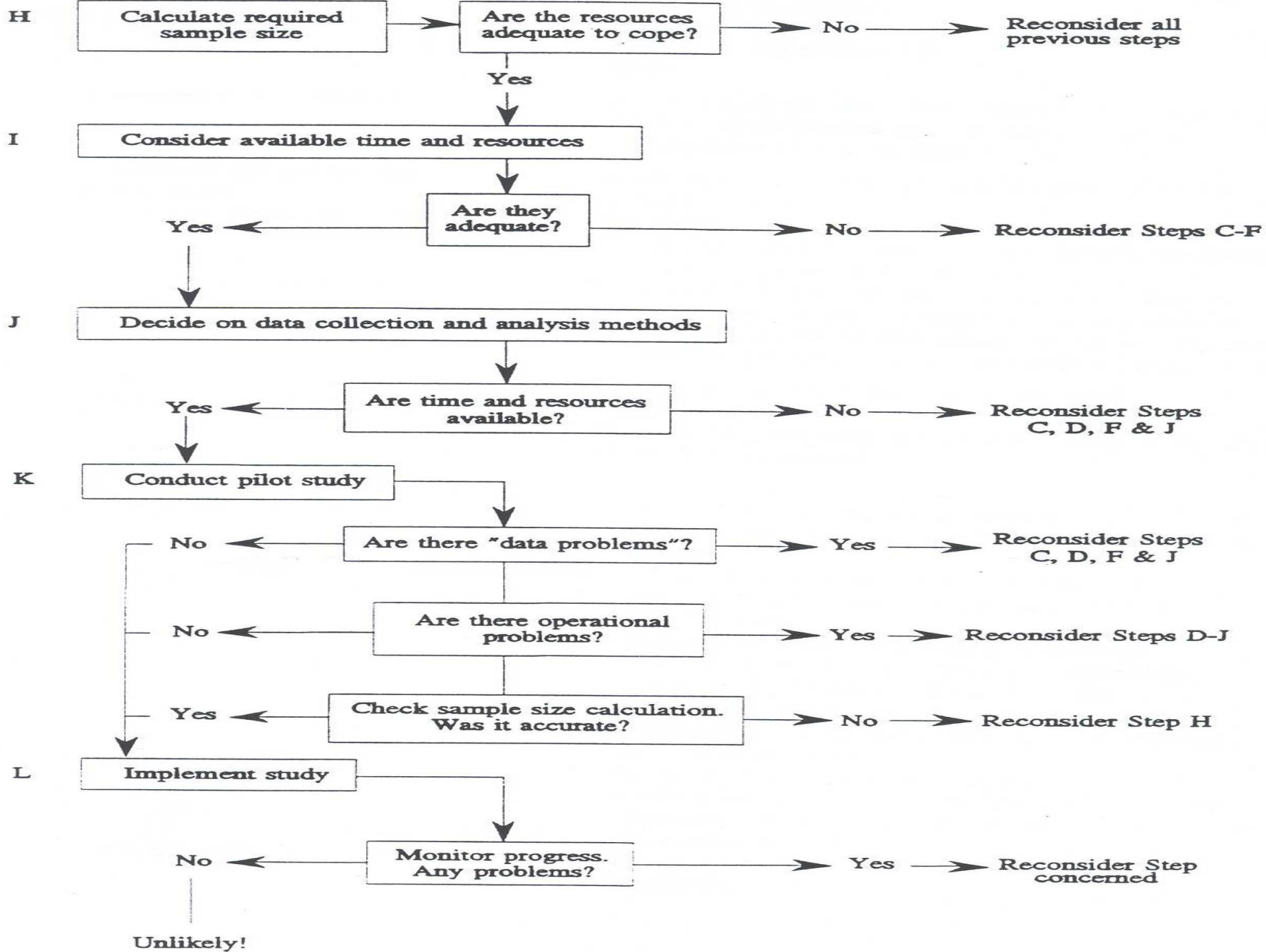
Common mistakes

- Including too little detail about proposed studies and insufficient justification for the significance of the problem
- Proposing far more work than can be reasonably done during the grant period

Step

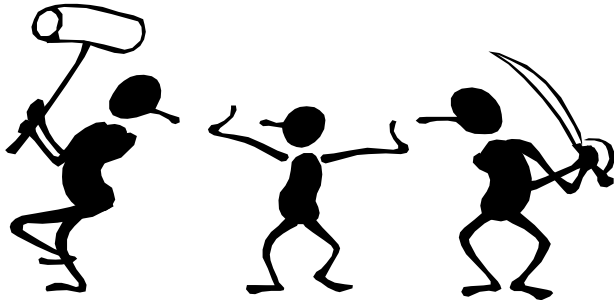
Iterative Procedure





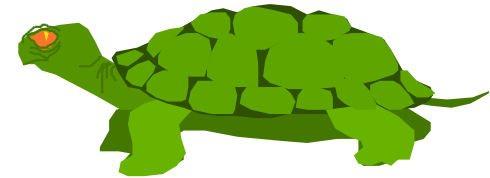
Writing Stages

1. Getting in the Mood

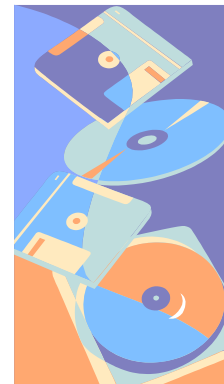


2. Writing the First Draft

Save **multiple** copies
of your draft



3. Revising, Revising, Revising



4. Finishing





Conclusions

- Developing, and communicating a research protocol is a sophisticated and time-consuming process.

It is important to understand the steps in developing a research protocol in order to perform an appropriate study and obtain reliable results.



Thank you !