Aim: Introduction

Objectives of this lecture

- The student understand
  - the resons beyond knowing
    - statistics as a medical doctor
- Describing
  - how this course is organized

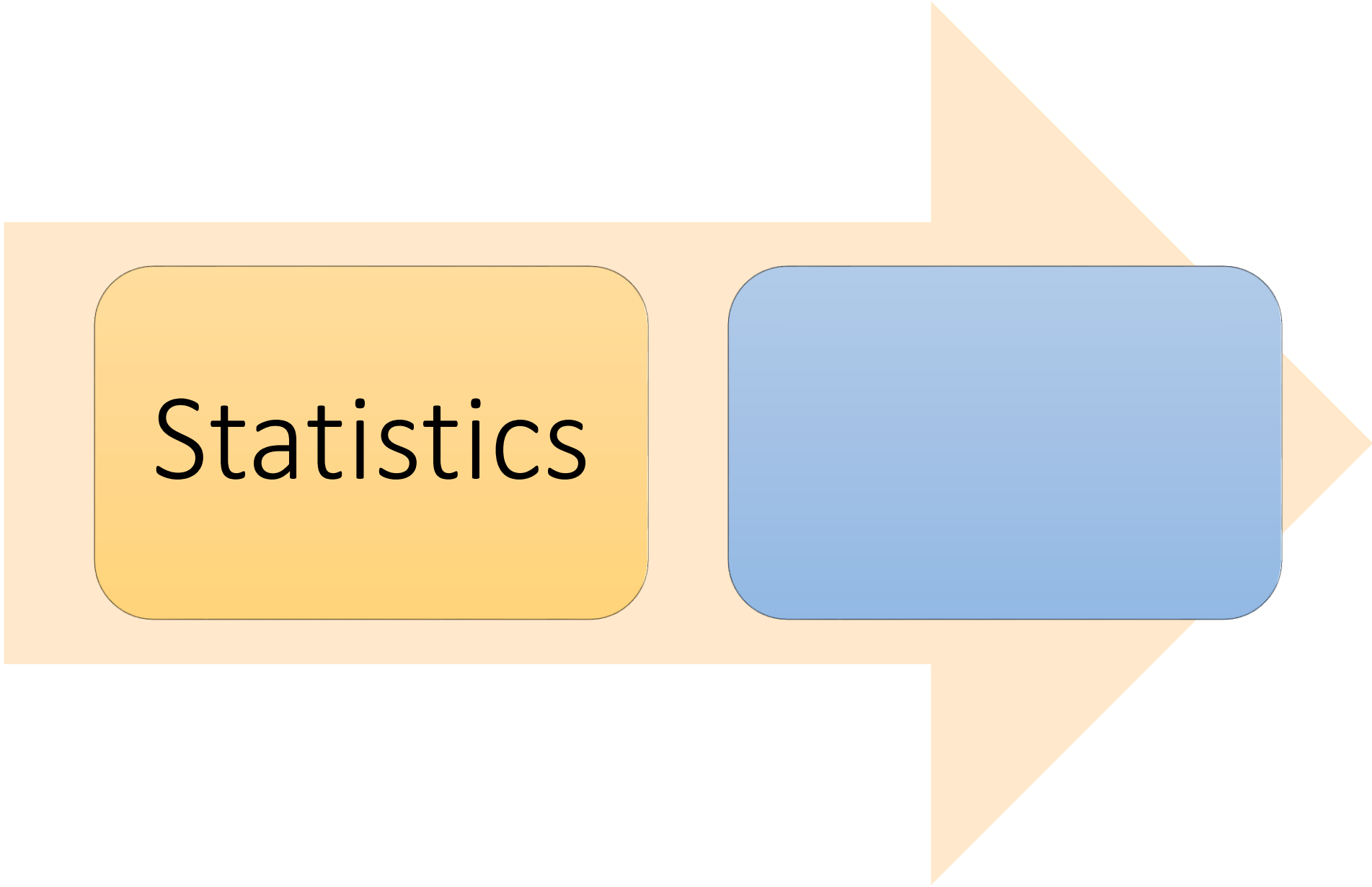
Bondor Cosmina-Ioana

- Assistant professor (Coferențiar)
- Phd in medicine
- Msc in Bioinformatics
- Computer scientist
- Mathematician
- Contact:
  - email cbondor@umfcluj.ro
  - Teams chat: Bondor Cosmina Ioana
- My academic profile

- ASK - feel free to ASK me anything, anytime

- I'll do my best to answer.

You are here for...


Statistics

Statistics

- populations
- describe
  - features (variables, data)
  - numbers (descriptive parameters)
- the process to analyse data = to make statistics

- Ex. the **votes** of a candidate in an election (in %),
- the number of **births** per year
- the average **temperatures** per months

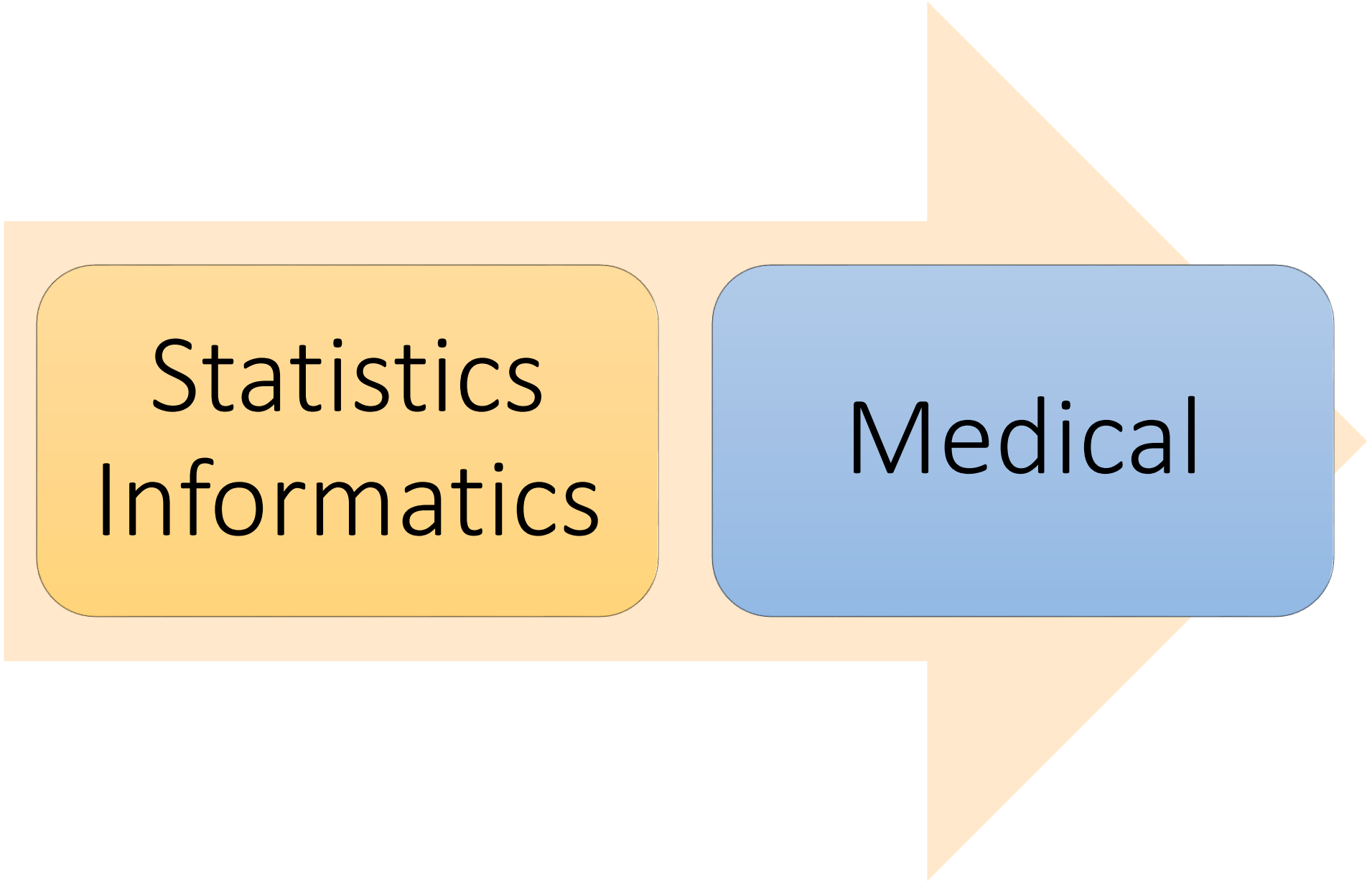
– median **survival** time in people with lung cancer

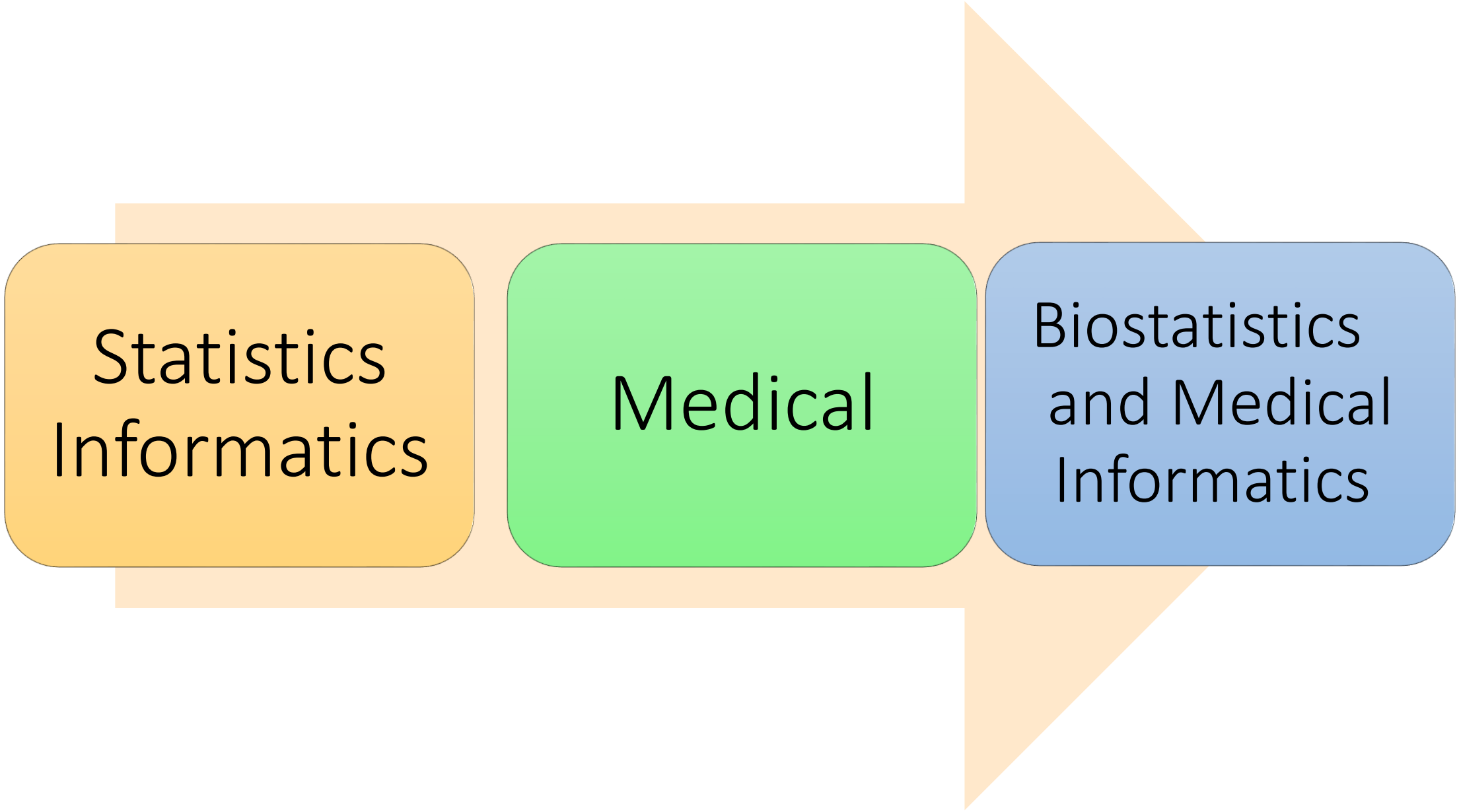
– the **percent** of people with diabetes in a region

– the **average** age when people get hypertension

Statistics – a part of

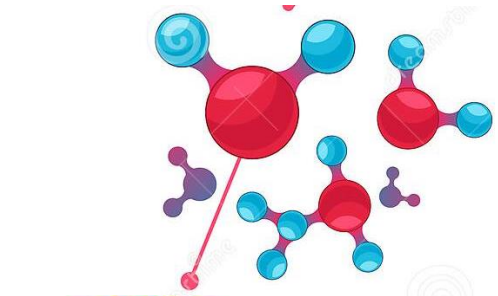
- Epidemiology – study of ilness and heath in populations
- Evidence-based medicine – apply it to decision making
- Bioinformatics – study of the genom

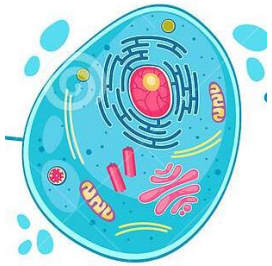

Statistics
Informatics
Medical

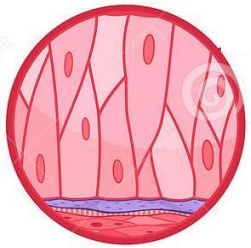

Statistics
Informatics
Medical
Biostatistics
and Medical
Informatics

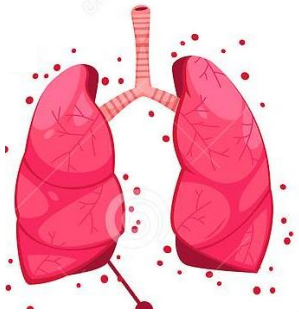
Why on Earth should we do statistics?

Diferent life forms









Molecul

Cell

Tisue

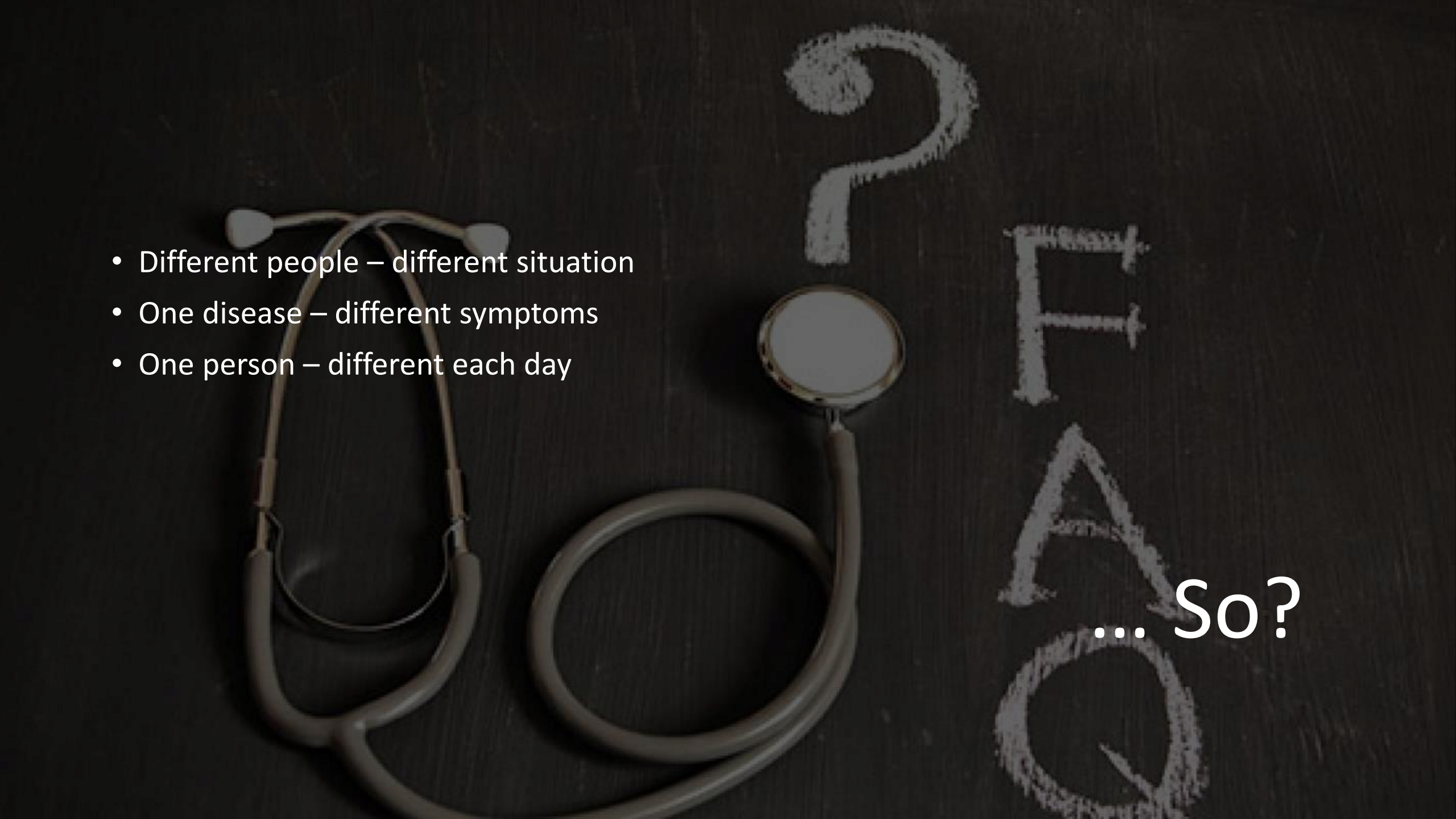
Organ

Multitude of life forms

Earth

People from Bihor county (Ro) – random selection: there are differences\there are similarities

Usually in life there is no such uniformity



- Different people – different situation
- One disease – different symptoms
- One person – different each day

… So?

Today

- we can treat **some** disease
- we can make correct dianostic **sometime**
- **sometime** we can predict the treatment results
- etc.

How did we get here?

The result of using biostatistics

500 BCE The world's "**first clinical trial**"

1747 CE **James Lind** the first physician to have conducted a controlled clinical trial.

1863 CE The first known use of a **placebo** in a clinical trial

1943 CE The first **double-blind comparative** clinical trial with concurrent controls in the general population

1946 CE **The first randomized control** trial of streptomycin

the use of biostatistics

- to describe populations
  - ex. to describe
    - people with depression
    - people who get anti inflamatory medication
    - bacteria from a gastrointestinal tract
- medical research
  - ex. to respond to questions
    - is sugar intake a cause of dental cavities?
    - is depression a cause of alcoholism?
    - can we treat obesity with physical activity?

Two objectives → Two domain of Biostatistics

- to describe populations/samples → Descriptive statistics
- making medical research → Inferential statistics

(to generalize results found in a sample to whole population)

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

CLINICAL PROBLEM

Safe and effective vaccines to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and Covid-19 are urgently needed. No vaccines that protect against betacoronaviruses are currently available, and mRNA-based vaccines have not been widely tested.

CLINICAL TRIAL

A randomized, double-blind study of an mRNA vaccine encoding the SARS-CoV-2 spike protein.

43,548 participants ≥16 years old were assigned to receive the vaccine or placebo by intramuscular injection on day 0 and day 21. Participants were followed for safety and for the development of symptomatic Covid-19 for a median of 2 months.

RESULTS

Safety:
Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reactions following the second dose. Most were mild to moderate and resolved rapidly.

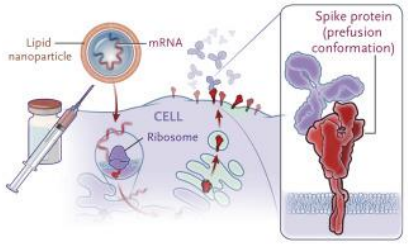
Efficacy:
The vaccine showed some early protection 12 days after the first dose; 7 days after the second dose, 95% efficacy was observed.

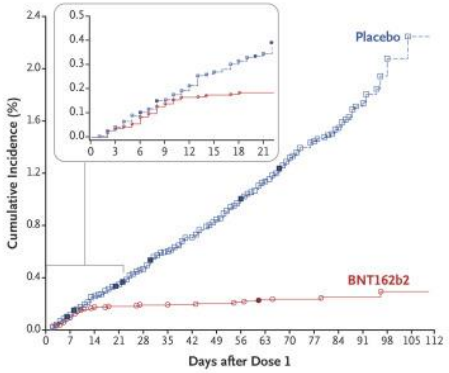
LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy beyond 2 months and in groups not included in this trial (e.g., children, pregnant women, and immunocompromised persons).
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to deal with those who miss the second vaccine dose.

Links: Full article | NEJM QuickTake | Editorial





	BNT162b2 Vaccine	Placebo
Symptomatic Covid-19	8	162
	N=18198	N=18325
Severe Covid-19	1	9
	N=21669	N=21686

Vaccine efficacy of 95% (95% credible interval, 90.3–97.6%)

CONCLUSIONS

Two doses of an mRNA-based vaccine were safe over a median of two months and provided 95% protection against symptomatic Covid-19 in persons 16 years of age or older.

Pfizer vaccine Covid-19

- First publish article
- Clinical trial on 43 548 participants
- Performed before approval and marketing of the vaccine

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

CLINICAL PROBLEM

Safe and effective vaccines to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and Covid-19 are urgently needed. No vaccines that protect against betacoronaviruses are currently available, and mRNA-based vaccines have not been widely tested.

CLINICAL TRIAL

A randomized, double-blind study of an mRNA vaccine encoding the SARS-CoV-2 spike protein.

43,548 participants ≥16 years old were assigned to receive the vaccine or placebo by intramuscular injection on day 0 and day 21. Participants were followed for safety and for the development of symptomatic Covid-19 for a median of 2 months.

RESULTS

Safety:
Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reactions following the second dose. Most were mild to moderate and resolved rapidly.

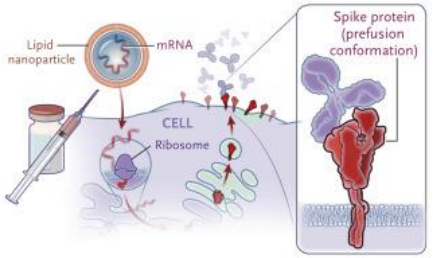
Efficacy:
The vaccine showed some early protection 12 days after the first dose; 7 days after the second dose, 95% efficacy was observed.

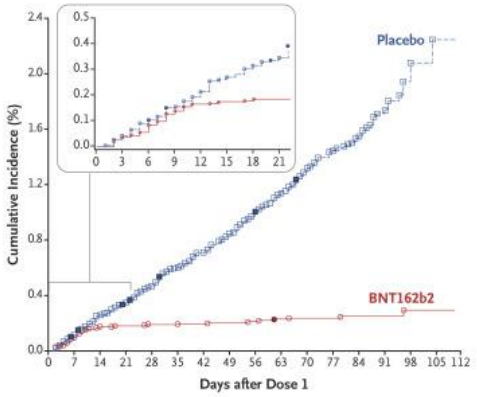
LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy beyond 2 months and in groups not included in this trial (e.g., children, pregnant women, and immunocompromised persons).
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to deal with those who miss the second vaccine dose.

Links: Full article | NEJM QuickTake | Editorial





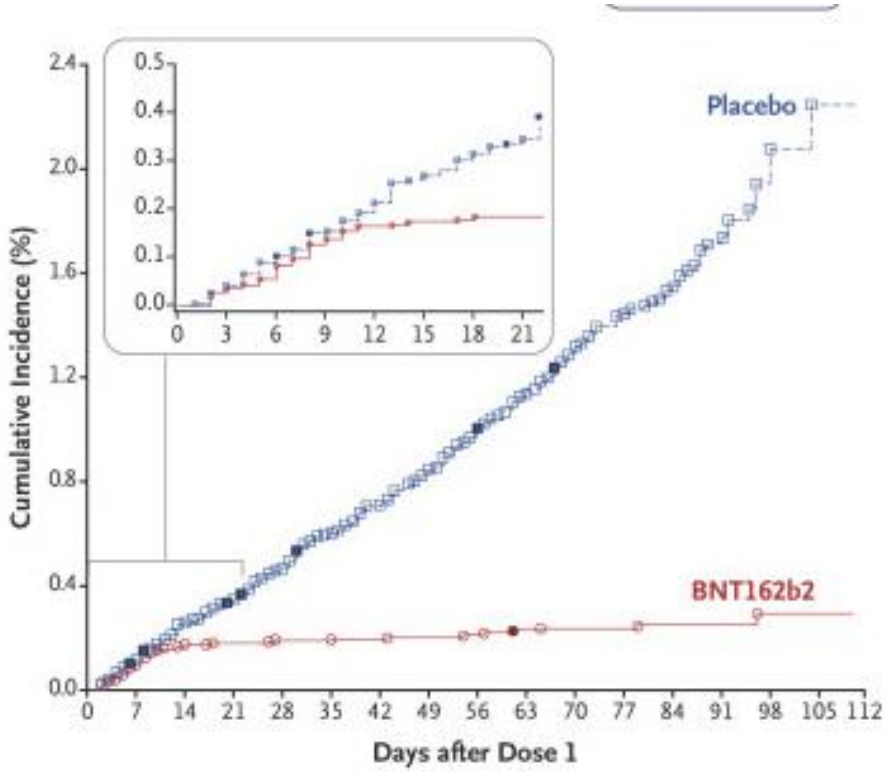
	BNT162b2 Vaccine	Placebo
Symptomatic Covid-19	8	162
	N=18198	N=18325
Severe Covid-19	1	9
	N=21669	N=21686

Vaccine efficacy of 95% (95% credible interval, 90.3–97.6%)

CONCLUSIONS

Two doses of an mRNA-based vaccine were safe over a median of two months and provided 95% protection against symptomatic Covid-19 in persons 16 years of age or older.

Pfizer vaccine Covid-19



- What does this chart mean?

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

CLINICAL PROBLEM

Safe and effective vaccines to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and Covid-19 are urgently needed. No vaccines that protect against betacoronaviruses are currently available, and mRNA-based vaccines have not been widely tested.

CLINICAL TRIAL

A randomized, double-blind study of an mRNA vaccine encoding the SARS-CoV-2 spike protein.

43,548 participants ≥16 years old were assigned to receive the vaccine or placebo by intramuscular injection on day 0 and day 21. Participants were followed for safety and for the development of symptomatic Covid-19 for a median of 2 months.

RESULTS

Safety:
Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reactions following the second dose. Most were mild to moderate and resolved rapidly.

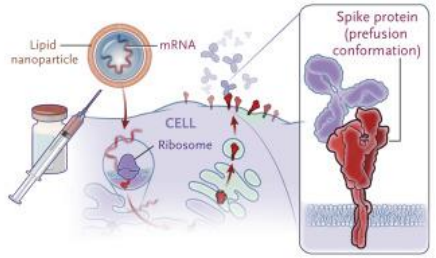
Efficacy:
The vaccine showed some early protection 12 days after the first dose; 7 days after the second dose, 95% efficacy was observed.

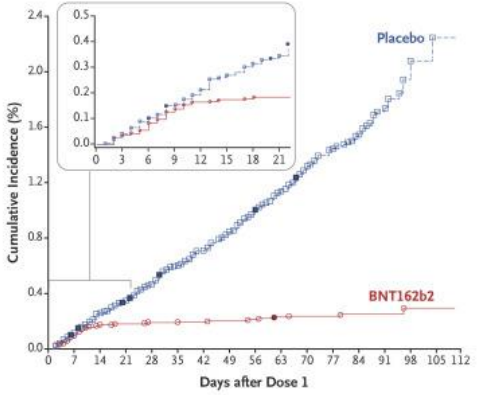
LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy beyond 2 months and in groups not included in this trial (e.g., children, pregnant women, and immunocompromised persons).
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to deal with those who miss the second vaccine dose.

Links: Full article | NEJM QuickTake | Editorial





	BNT162b2 Vaccine	Placebo
Symptomatic Covid-19	8	162
	N=18198	N=18325
Severe Covid-19	1	9
	N=21669	N=21686

Vaccine efficacy of 95% (95% credible interval, 90.3–97.6%)

CONCLUSIONS

Two doses of an mRNA-based vaccine were safe over a median of two months and provided 95% protection against symptomatic Covid-19 in persons 16 years of age or older.

Pfizer vaccine anti – Covid-19

	BNT162b2 Vaccine	Placebo
Symptomatic Covid-19	8	162
	N=18198	N=18325
Severe Covid-19	1	9
	N=21669	N=21686

Vaccine efficacy of 95% (95% credible interval, 90.3–97.6%)

- What does this mean?

Medical research is based on statistics

Objectives

- The student will be provided with the tools and skill to become a consumer of
  - Published articles
  - Medical research
- The student should know
  - Where to get the information
  - How to search for medical information

Biostatistics and Medical Informatics
(first semester, first year)

Metodology of the Medical Research
(second semester, Second year)

First...
biostatistics

• Evaluating the literature - the published results of research

- researchers (publish or perish)
- journals
- pharma industry

→ have interest to **publish !!!**

- medical doctors
- dentist
- nurse

→ have interest to **treat patients efficient** → have interest to **read medical literature**

Reasons learning statistics →

decide whether you can **believe** the results presented in the literature

Bibliography

- “Doctors need training in order to critically appraise the quality of available evidence instead of taking all published literature on trust” *(Ioannidis et al., 2017)*
- **“Only about 20% of 4235 research reports met the criteria for validity”** *(Williamson et al., 1992).*
- “It has been estimated that 85% of all research funding is actually wasted, due to inappropriate research questions, faulty study design, flawed execution, irrelevant endpoints, poor reporting and/or non-publication” *(MacLeod et al., 2014; Moher et al., 2016).*
- Book: Cohen AL. Problems and Pitfalls in Medical Literature. A Practical Guide for Clinicians. 2023
  https://link.springer.com/book/10.1007/978-3-031-40295-1
- Book: Smith R. The trouble with medical journals. J R Soc Med. 2006
  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1383755/

Bibliography

- “Doctors need training in order to critically appraise the quality of available evidence instead of taking all published literature on trust” *(Ioannidis et al., 2017)*
- **“Only about 20% of 4235 research reports met the criteria for validity”** *(Williamson et al., 1992).*

85% research funding - wasted, due to
- inappropriate research questions,
- faulty study design,
- flawed execution,
- irrelevant endpoints,
- poor reporting
- non-publication

*(MacLeod et al., 2014; Moher et al., **2016**)*

esearch fund
y study desig
d/or non-pu

it

-3-031-40295-1

al journals. J
PMC1383755/

Your task (medical doctor) – to understand and identify the 20% valid literature

My task - to teach you how to do that.

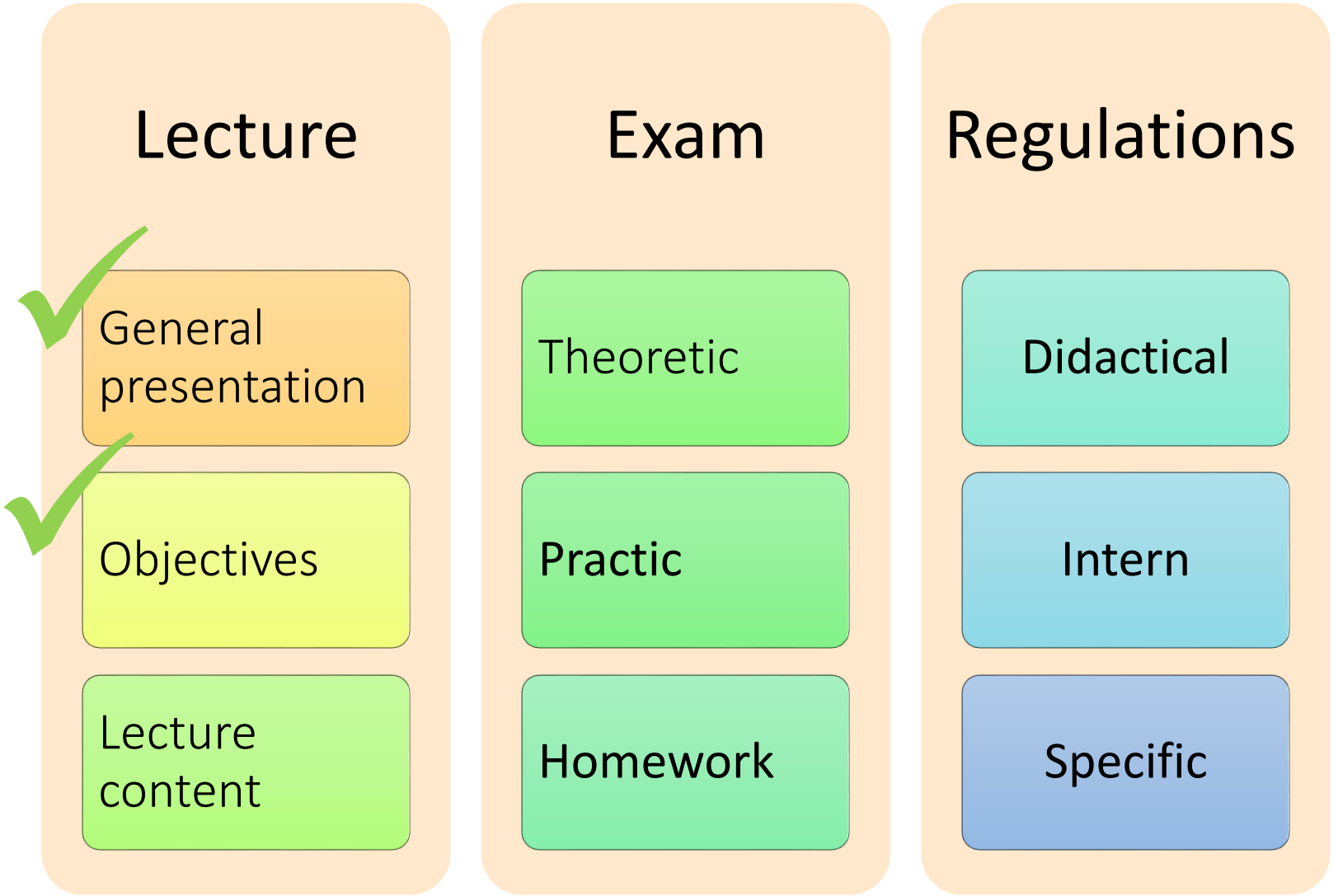
Professional competences	• conducts health research • informs decision-makers about health challenges • use e-health and mobile health technologies
Transversal competences	• communication, • critical thinking, • lifelong learning • time management skills • team organization and coordination skills

General objectives of the course	The Medical Informatics and Biostatistics discipline aims to introduce students to the fundamental methods of medical data analysis and the use of modern information technologies, essential in the practice of medicine. At the end of the course, students will be able to: • understand and apply descriptive and inferential analysis on a given clinical scenario • to know the main applications of information technology in the medical field. • record health care users data

Learning outcomes (LO)	**Knowledge (K)** At the end of the course, students will be able to: K1. Explain the principles of conducting searches in online medical databases (e.g., PubMed). K2. Describe the technical steps and design principles for creating effective and professional presentations to disseminate medical knowledge. K3. Identify and describe the types of variables involved in medical data collection. K4. Explain the principles of designing and constructing databases for recording medical data. K5. Define descriptive statistical parameters and explain their appropriate use in data analysis. K6. Demonstrate knowledge of theoretical and empirical probability. K7. Explain the principles of estimating population parameters based on sample data. K8. Describe statistical methods used in inferential statistical analysis within the medical field. K9. Interpret the results of statistical analyses and apply them to medical decision-making

Learning outcomes (LO)	Skills (S) - The student will demonstrate the ability to: S1. Effectively search for medical information using dedicated databases such as PubMed and others. S2. Create and deliver effective, professional presentations for the dissemination of medical knowledge. S3. Draft medical documents using Microsoft Word, applying appropriate formatting and structure. S4. Accurately identify variable types involved in medical data collection processes. S5. Collect and organize medical data using Microsoft Excel. S6. Based on variable types and research objectives, determine the appropriate descriptive methods for presenting medical data, and implement these using Microsoft Excel and Jamovi. S7. In clinical scenarios, identify relevant events and accurately determine their theoretical or empirical probabilities. S8. Accurately estimate population parameters based on data derived from a representative sample. S9. Select and apply appropriate statistical methods for inferential analysis in medical contexts using Jamovi. S10. Interpret the results of statistical analyses correctly and apply them to support evidence-based medical decision-making.

Administrative issue


Lecture
General presentation
Objectives
Lecture content
Exam
Theoretic
Practic
Homework
Regulations
Didactical
Intern
Specific

SEMESTER I

29th September 2025 – 19th December 2025

- Didactic activity
- 12 weeks

22th December 2025 – 2nd January 2026

- Vacation
- 2 weeks

5th January 2026 – 9th January 2026

- Didactic activity
- 1 week

12th January 2026 – 16th January 2026

- Didactic activity
- Practical exam
- 1 week

19th January 2026 – 13th February 2026

- Exam session
- 4 weeks

16th February 2026 – 20th February 2026

- Vacation
- 1 week

Didactic activity

- Lecture
  - 14 weeks = 14 lecture
  - 1 hour each
    - Introduction
    - 12 lectures
    - Recapitulation

Week	Data	Course activity
01	29th September	C01 – Introduction
02	6th October	C02 – Descriptive statistics 1
03	13th October	C03 – Descriptive statistics 2
04	20th October	C04 – Descriptive statistics 3
05	27th November	C05 – Probabilities
06	3th November	C06 – Probabilities distribution. Sampling
07	10th November	C07 – Confidence intervals
08	17th November	C08 – Inferencial statistics 1
09	24th November	C09 – Inferencial statistics 2
10	1th December	C10 – Inferencial statistics 3
11	8th December	C11 – Inferencial statistics 4
12	15th December	C12 – Medical Informatics 1
13	5th January	C13 – Medical Informatics 2
14	12th January	C14 – Recapitulation

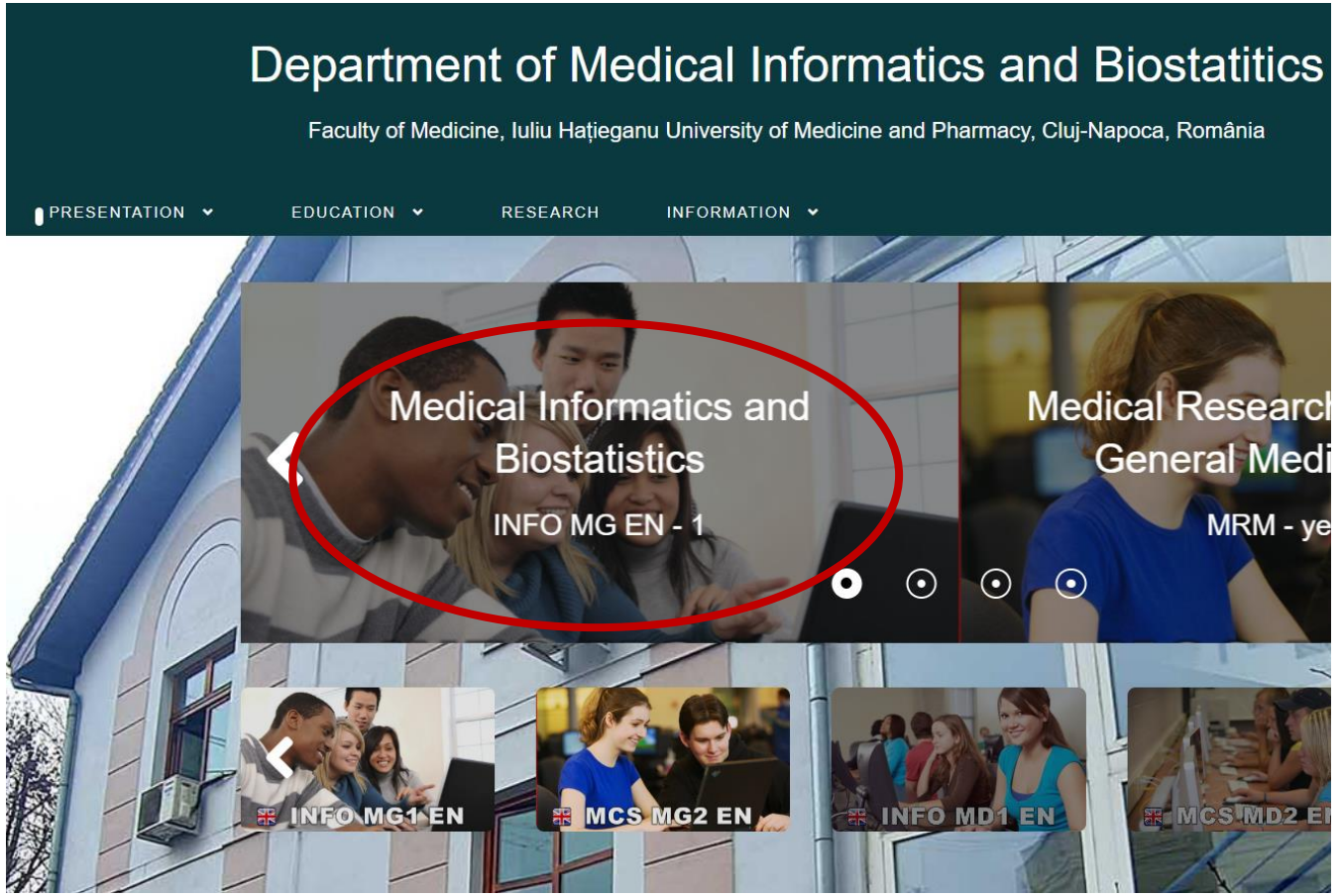
Bibliography

- Sorana BOLBOACĂ, Horaţiu COLOSI, Tudor DRUGAN, Andrei ACHIMAŞ, Ştefan ŢIGAN, **Elements of Medical Informatics and Biostatistics**, SRIMA Publishing House, Cluj-Napoca, Romania, 211 pages, 2003, ISBN 973-85285-0-X.
- Bernard ROSNER, Fundamentals of Biostatistics. 8th ed., Brooks/Cole, Cengage Learning, 2021. or other edition

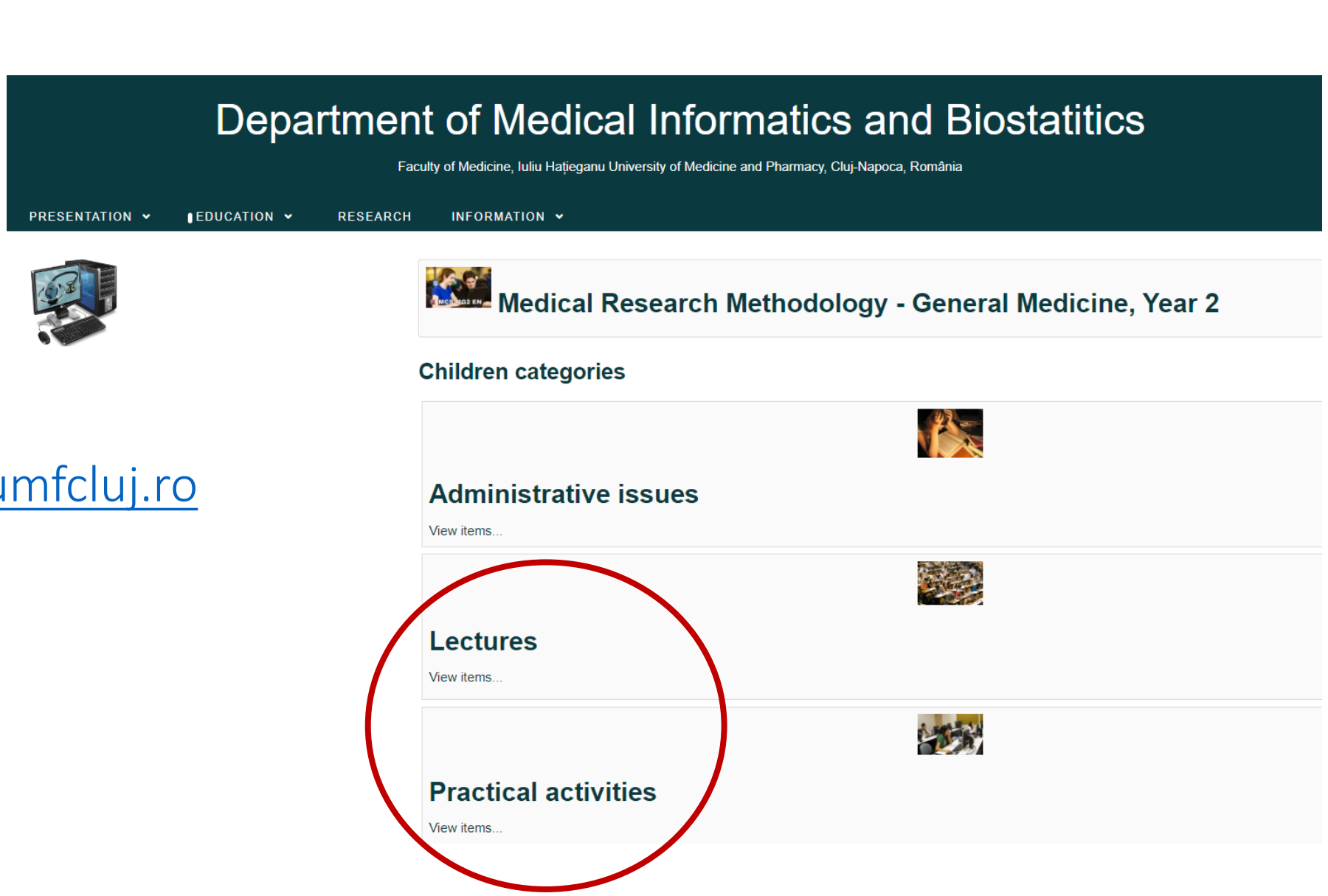
Didactic activity

- Practical activities (PA)
  - 14 weeks = 14 PA
    - Introduction
    - 11 PA's
    - Recapitulation, Exam example
    - Practical part of the exam

Site:
http://www.info.umfcluj.ro



Site:
http://www.info.umfcluj.ro



First practical activity

Practical Activity 02: Formulas and Functions

Eliminatory subjects for the practical exam:

- Working with Microsoft Excel: formulas, functions

Read **16** times

Published in Practical activities

Download attachments: LP1_request_Formulas_and_Functions.pdf (24 Downloads)
LP1_Hints_Formulas_and_Functions.docx (20 Downloads) LP1_optional_Formula_and_Functions.doc (18 Downloads)

First practical activity

Practical Activity 02: Formulas and Functions

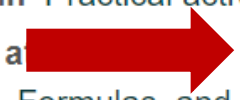
Eliminatory subjects for the practical exam:

- Working with Microsoft Excel: formulas, functions

Read **16** times

Published in Practical activities

Download a LP1_request_Formulas_and_Functions.pdf (24 Downloads)
LP1_Hints_Formulas_and_Functions.docx (20 Downloads) LP1_optional_Formula_and_Functions.doc (18 Downloads)



- **Compulsory to follow request**

First practical activity

Practical Activity 02: Formulas and Functions

Eliminatory subjects for the practical exam:

- Working with Microsoft Excel: formulas, functions

Read **16** times

Published in Practical activities

Download a LP1_request_Formulas_and_Functions.pdf (24 Downloads)
LP1_Hints_Formulas_and_Functions.docx (20 Downloads) LP1_optional_Formula_and_Functions.doc (18 Downloads)

- **Compulsory to follow request**
- Hints

Practical activity 1

Practical Activity 02: Formulas and Functions

Eliminatory subjects for the practical exam:

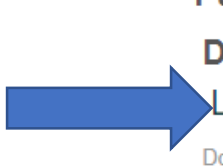
- Working with Microsoft Excel: formulas, functions

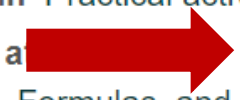
Read **16** times

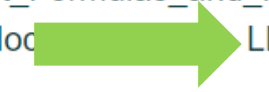
Published in Practical activities

Download a LP1_request_Formulas_and_Functions.pdf (24 Downloads)

LP1_Hints_Formulas_and_Functions.doc LP1_optional_Formula_and_Functions.doc (18 Downloads)







- **Compulsory to follow request**
- Hints
- Optional request
- Other necessary files

Regulation - student obligation

- **Lecture**
  - Minimum 70% attending
  - The presence will be taken

Regulation - student obligation

- **Practical activities**
- Minimum 100% attendance
  - The presence will be recorded
- Maximum 2 absences
  - Medical motivation or with payment
  - Recuperation
- ! All 11 practical activities must be done

Regulations

- **Exemption from the practical part of the exam !!!**
- Students who
  - Didn't recuperate all the absences in time
  - Have more than 2 absences at PA
  - Suspended
    - see the internal rules
      - rules which will be presented at the PA

Regulations

- **Exemption from the theoretical part of the exam !!!**
- Students who
  - Didn't pass the practical exam
  - Did not attend minimum 70% of the lectures

Regulation - student rights

- **To attend the examination**
  - **once / examination session**
  - **3 times / year**
- Winter session
- Re-examination I session
  - 13th July 2026 – 17th July 2026
- Re-examination II session
  - 14th September 2026 – 18th September 2026

Evaluation

Type of learning activity	Assessment criteria	Learning outcomes assessed	Assessment methods	Weight in final grade
Lecture	Correctness of answers to multiple responses question; Ability to synthesize and integrate knowledge from the taught topics.	K1, K2, K3, K4, K4, K5, K6, K7, K8, K9	Written exam, 35 multiple choice question	70%
Practical activity	Correctness of execution of the requirements; Ability to identify and correct mistakes in real time; Accuracy and quality of the final result; Explanation of the clinical or statistical reasoning; Compliance with the allotted time.	S2, S3, S4, S4, S5, S6, S7, S8, S9, S10	Practical exam, at computer, making documents/ power point presentation, using Microsoft Excel, Jamovi to analyses data, and interpret the results	30%
Minimum performance standard – obtain 5 in both exam				

Theoretical exam - 35 questions: 100 minutes to respond

- you will receive an A4 **paper with formulas**

If you score more than 13.7 points from 35 maximum, you may receive an additional max 3 bonus points for your responses to wooclap quiz (log with your user or with your name) during the course.

8) * The following are days of incubation for a contagious disease: 7; 3; 4; 7; 6; 6; 4; 5; 3; 7; 5; 4; 7; 6; 2; 3; 5; and 6. Coefficient of variation is equal to:
a) 0.32
b) 0.23
c) 0.27
d) 0.29
e) Could not be calculated based on provided data

Only one correct !

16) Let be a statistical series with the following data: 40, 60, 20, 20, 60, 80, 80, 40, 60, and 80. The relative frequency of 0.3 corresponds to:
a) 20
b) 40
c) 60
d) 80
e) None is correct

Two correct answers !

7) The following data represent the age of first episode of myocardial infarction on a series of male patients: 38, 50, 23, 45, 70, 33, 25, 40, 50, 62, and 59. The values of quartiles are as follows: Q1 = 35.5, Q2 = 45 and Q3 = 54.5. The following statements are true:
a) Q2 - Q1 = 9.5
b) Q3 - Q2 = 9.5
c) Data are asymmetrical distributed
d) Data are symmetrical distributed
e) Data are approximately symmetrical distributed

>2 answers correct !

Final Mark

- If the student obtain
  - minimum 5 at practical part of the exam
  - respectively minimum 5 at theoretical part of the exam
- The final mark will be computed

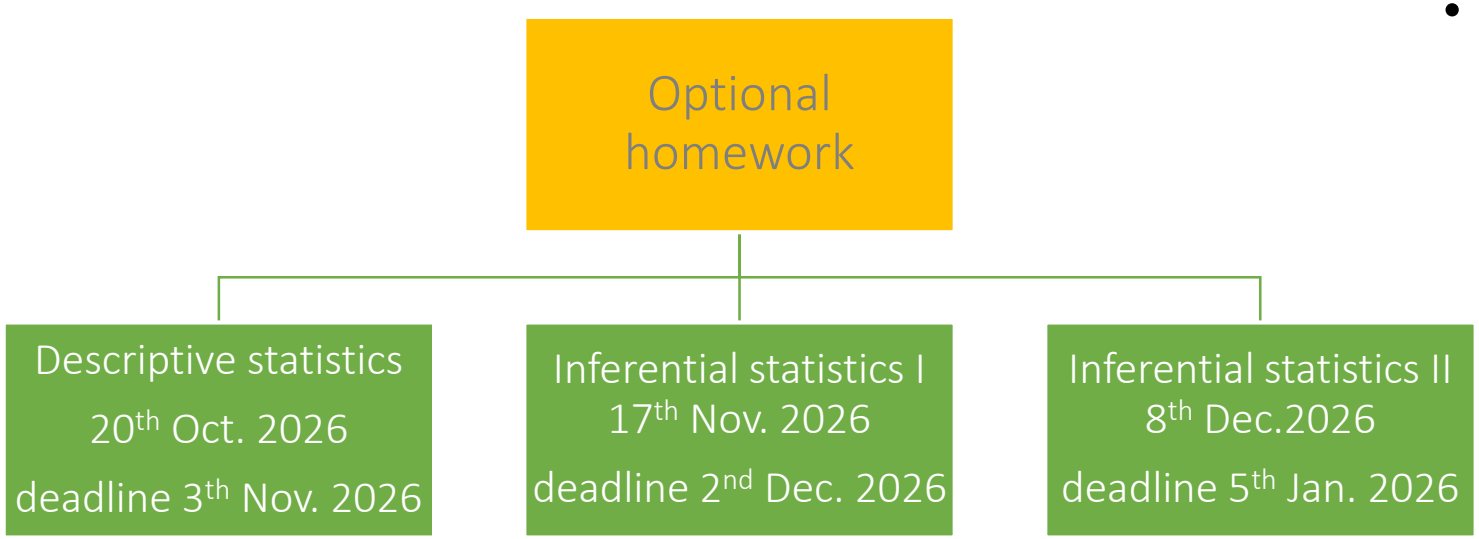
Final Mark

- Weighted mean
  - Theoretic exam - 70%
  - Practical exam - 30%
  - Weighted mean = 0.70*theoretic exam mark+0.30*practical exam mark

- If final mark < 10, but greater than 5

  → Final mark = weighted mean + 0.2*optional homework

Optional homework:



- deadlines!!!
- If you obtain minimum 5 at the submitted (quiz in Teams) homework
  - Final mark = weighted mean + 0.2*no. of optional homework (with mark≥5)

Department of Medical Informatics and Biostatitics

Faculty of Medicine, Iuliu Haţieganu University of Medicine and Pharmacy, Cluj-Napoca, România

Practical activities

Practical Activity 01 - Organizational Measures

Practical Activity 02: Formulas and Functions

Practical Activity 03 - Descriptive statistics for qualitative variable

Practical Activity 04 - Descriptive statistics for quantitative variable

Practical activity 04 bis - Homework 1 - for lecture

Practical activity 05 - Probabilities

Objectives of optional - supplementary work

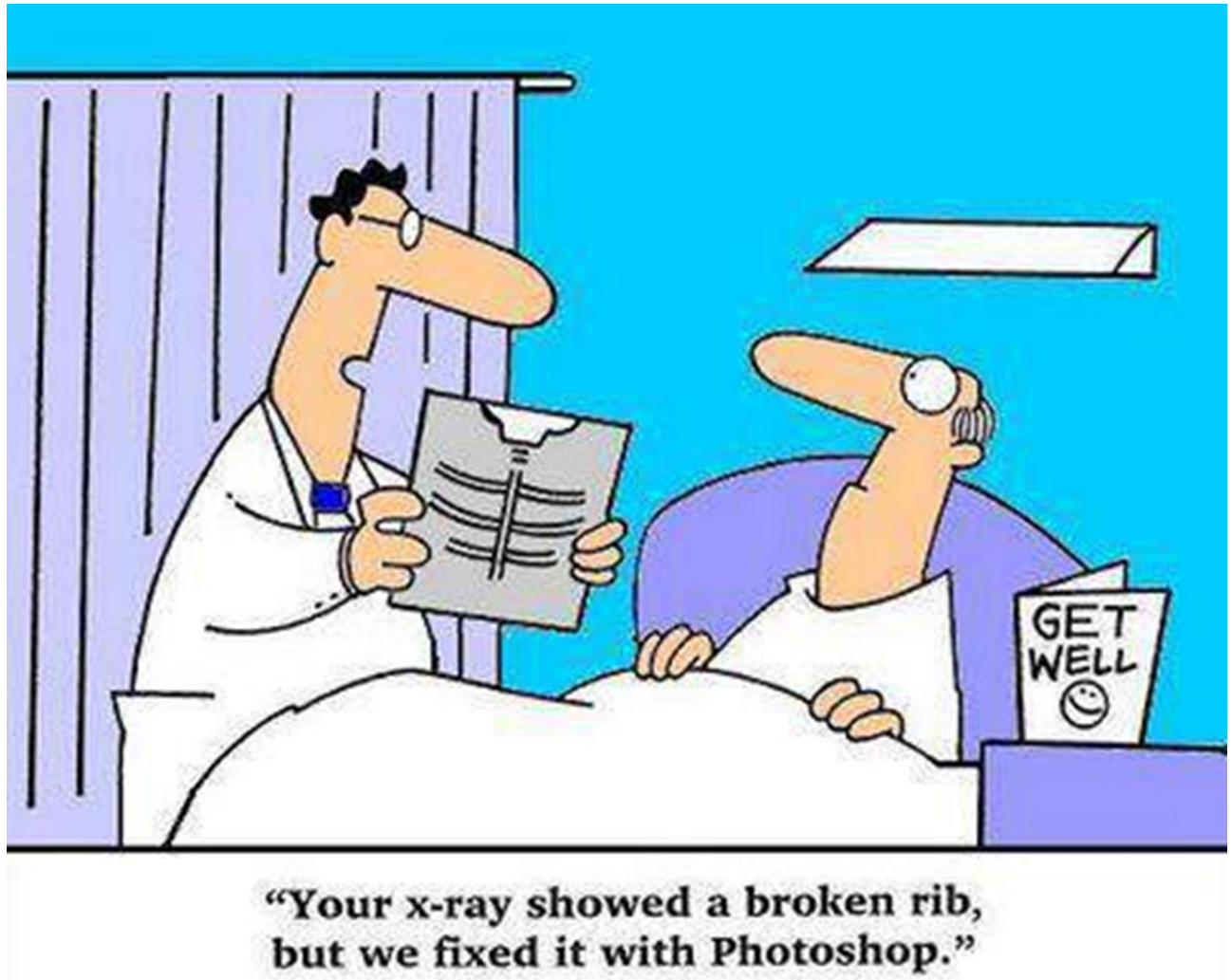
- To help student to pass the exam
  - if no/week computer competencies --> doing the **suplementary work from practical activity** will help you

- try to understand what are you doing at PA (not only follow the requests and hints)
    - if you know how to make the supplementary work → Probability to take the practical exam is high

- homework
  - similar to theoretical exam
  - if you make the homework by yourself --> Probability to take the theoretical exam is high

Conclusion

- 14 PA – one each week
  - 75%-100% from compulsory activities must be done during each PA = presence at PA
  - <75% from compulsory activities during the PA = absence at PA
- Maximum 2 absences at PA
  - All made-up (with medical motivation, payment an aditional fee)
- Practical exam in the last week during PA
- Minimum 5 at practical part of the exam --> pass -->
- --> minimum 70% attendance to lecture --> theoretical part of the exam during session--> minimum 5 at theoretical exam -->
- Done



"Your x-ray showed a broken rib,
but we fixed it with Photoshop."

Thank you!