



Aim: Introduction

Objectives of this lecture

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

Bondor Cosmina-Ioana

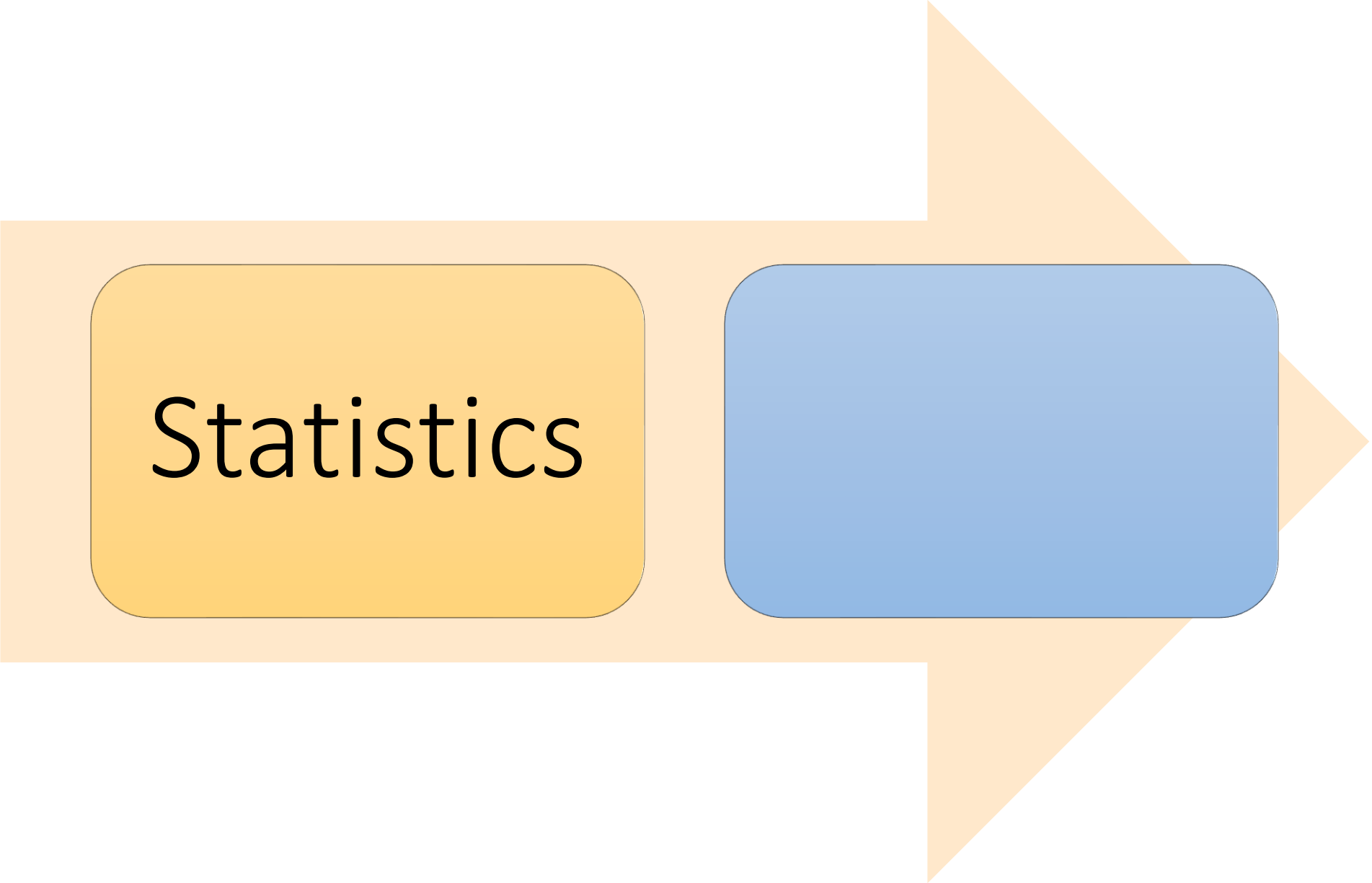
- Assistant professor (Conferențiar)
- Phd in medicine
- Msc in Bioinformatics
- Computer scientist
- Mathematician
- Contact:
 - email cbondor@umfcluj.ro
 - Teams chat: Bondor Cosmina Ioana
- [My academic profile](#)





- **ASK** - feel free to **ASK**
- I'll do my best to answer.

You are here for...



Statistics

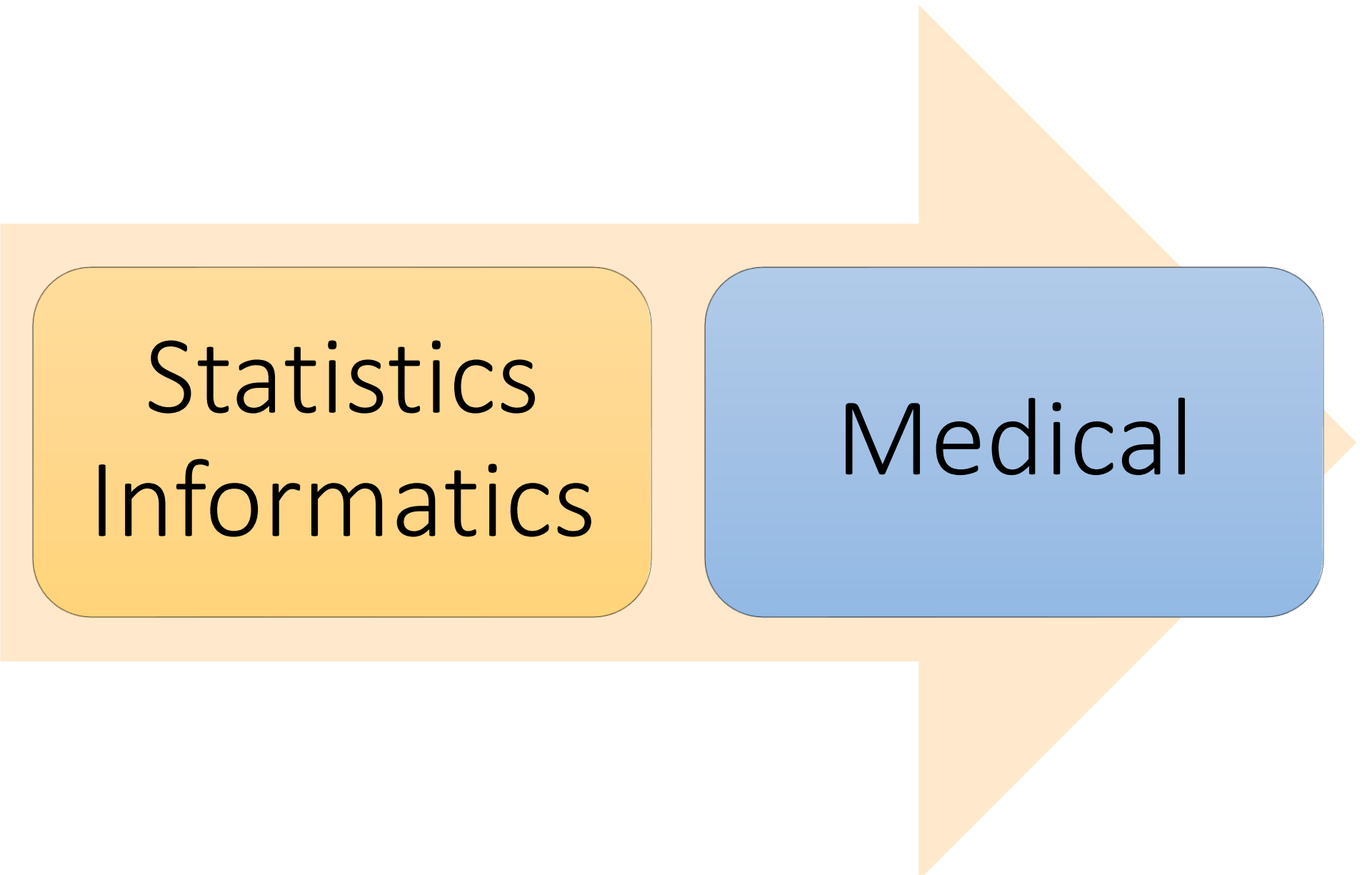
Statistics

- 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 %),
 - median **survival** time in people with lung cancer
- the number of **births** per year
 - the **percent** of people with diabetes in a region
- the average **temperatures** per months
 - the **average** age when people get hypertension

Statistics – a part of

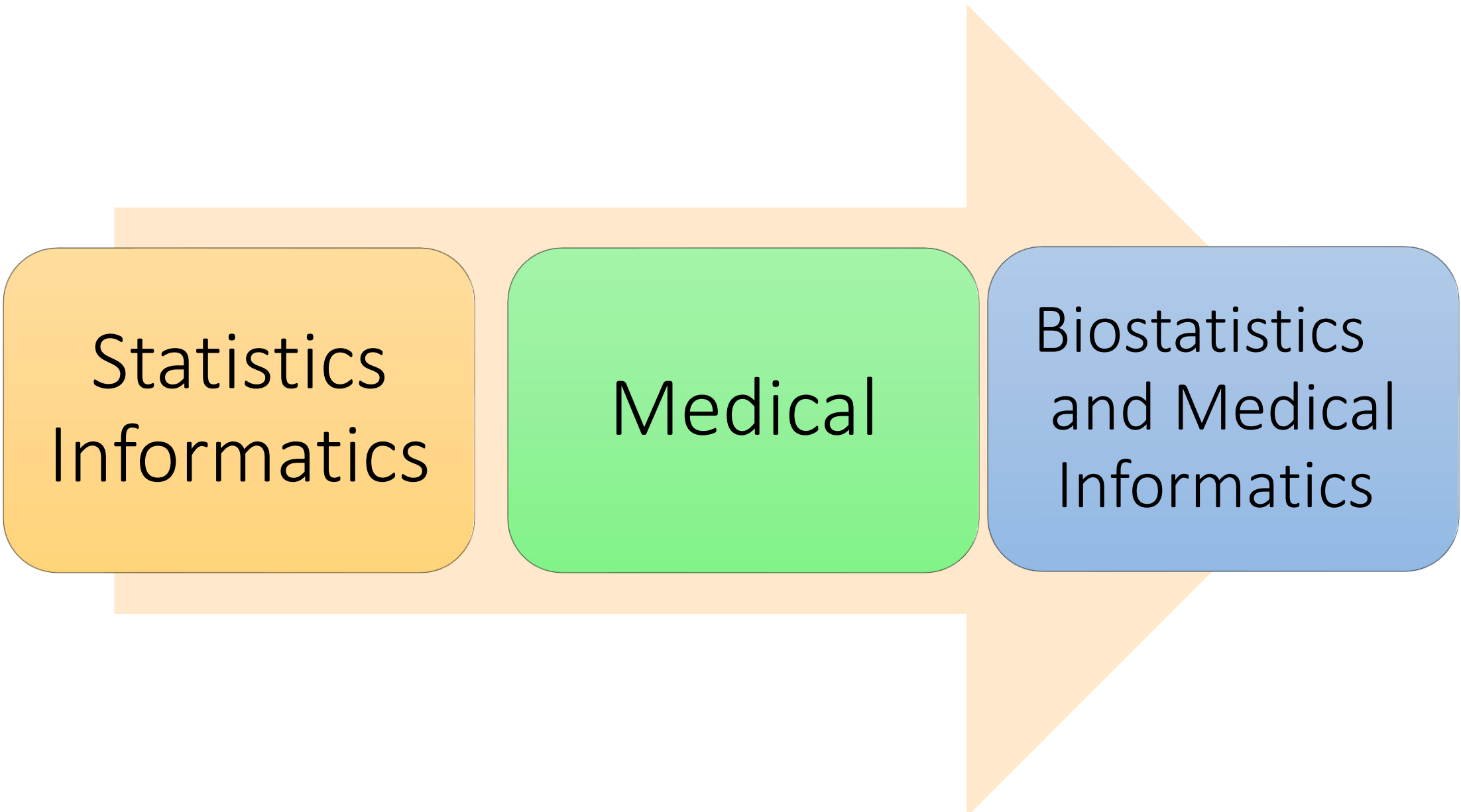
- Epidemiology – study of illness and health in populations
- Evidence-based medicine – apply it to decision making
- Bioinformatics – study of the genome
- Artificial intelligence
 - LLM – reasoning (statistics is the core foundation)
 - Knowledge discovery
 - Data mining



The diagram features a large, light orange arrow pointing to the right. Inside the arrow's shaft are two rounded rectangular boxes. The left box is orange and contains the text 'Statistics Informatics'. The right box is blue and contains the text 'Medical'. The boxes are positioned side-by-side, suggesting a flow or relationship between the two fields.

Statistics
Informatics

Medical



Statistics
Informatics

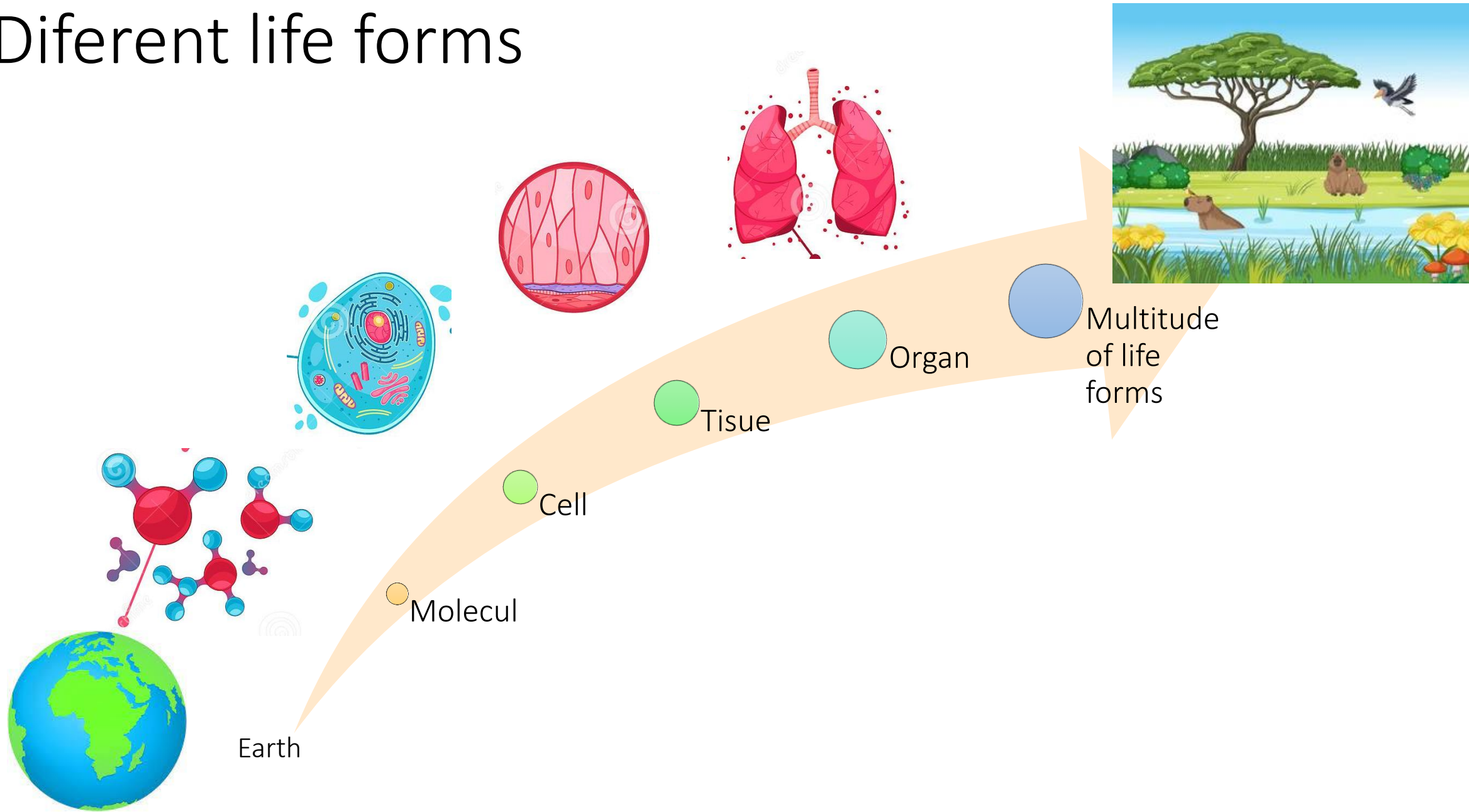
Medical

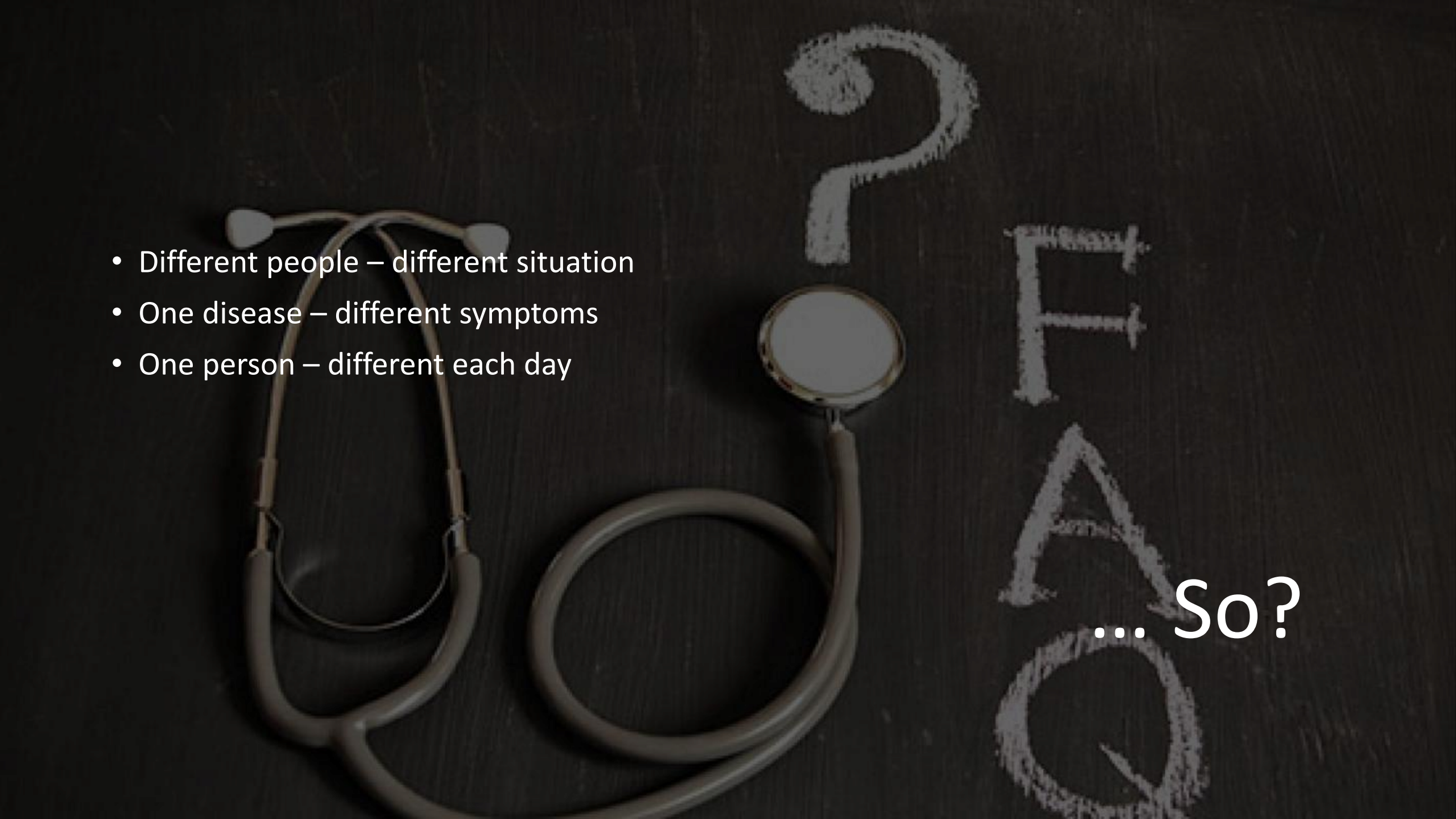
Biostatistics
and Medical
Informatics

Why on Earth should we do statistics?



Diferent life forms



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

... So?

Today

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

How did we get here?

The result of using
biostatistics

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



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

1747 CE

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

1946 CE

500 BCE

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



1863 CE

1943 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 inflammatory 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)

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:

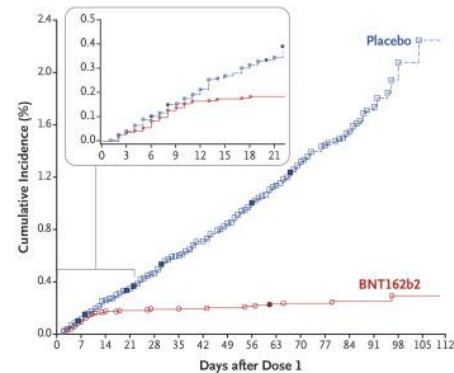
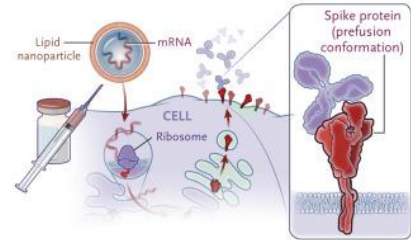
The vaccine showed some early protection 12 days after the first dose; 7 days after the second dose, 95% efficacy was observed.

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

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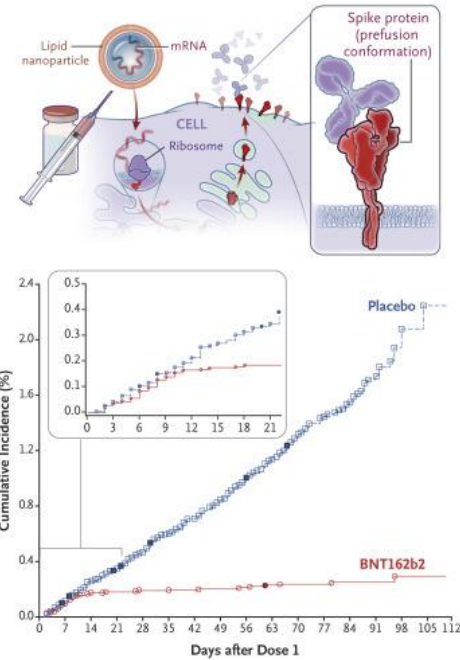
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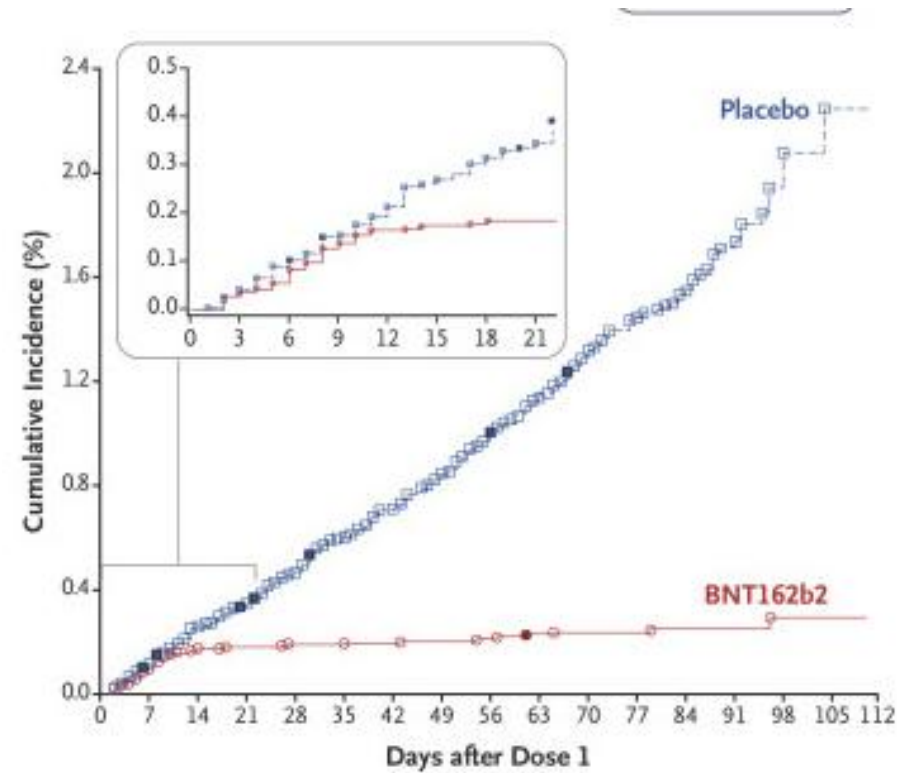
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Pfizer vaccine Covid-19



- What does this chart mean?

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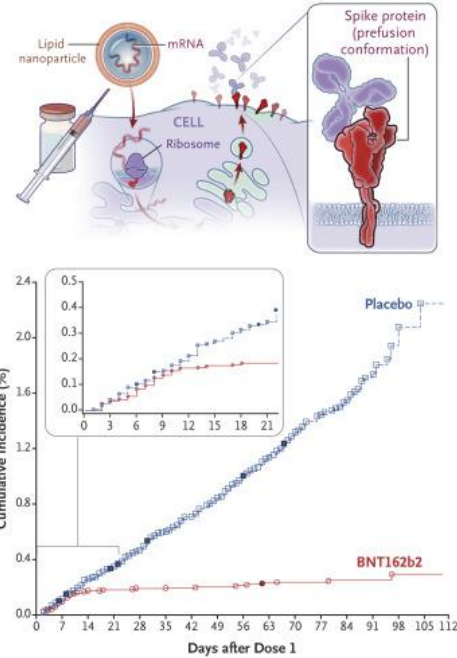
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- What does this mean?

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)

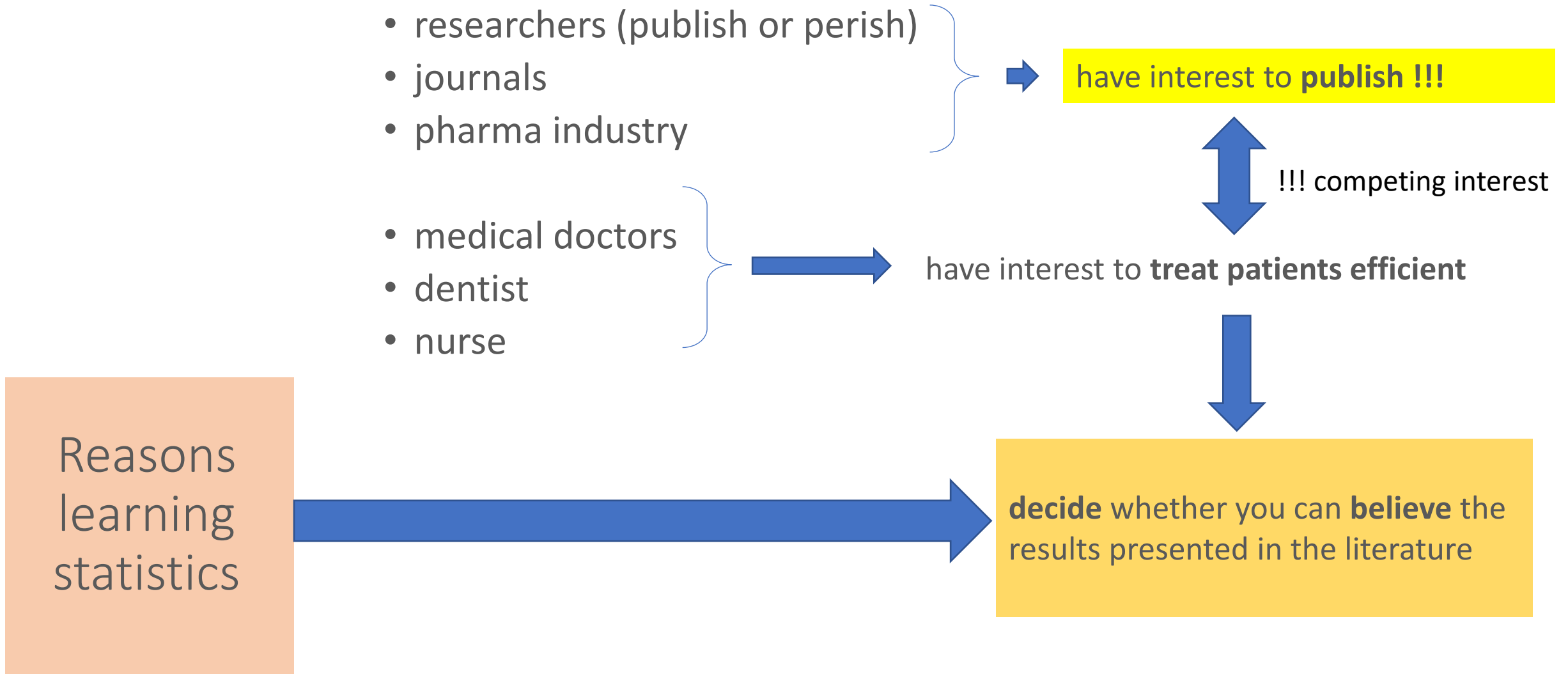


Medical Research Methodology
(second semester, Second year)

First...
biostatistics



- Evaluating the literature - the published results of research



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

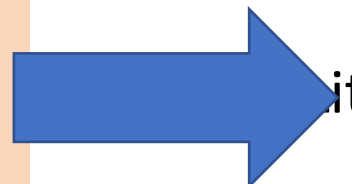
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85% research funding - wasted, due to

- inappropriate research questions,
- faulty study design,
- flawed execution,
- irrelevant endpoints,
- poor reporting
- non-publication

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

research funding
study design
and/or non-published



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al journals. J
/PMC1383755/

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

My task: to teach you how to do it

Administrative issue

Lecture



General presentation



Objectives

Lecture content

Exam

Theoretic

Practic

Homework

Regulations

Didactical

Intern

Specific

SEMESTER I

28th September
2026 – 18th
December 2026

- Didactic activity
- 12 weeks

21th December
2025 – 8th
January 2026

- Vacation
- 3 weeks

11th January
2026 – 15th
January 2026

- Didactic activity
- 1 week

18th January
2026 – 22th
January 2026

- Didactic activity
- Practical exam
- 1 week

25th January
2026 – 19th
February 2026

- Exam session
- 4 weeks

22th February
2026 – 26th
February 2026

- Vacation
- 1 week

Didactic activity

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

Week	Data	Course activity
01	28 th September	C01 – Introduction
02	5 th October	C02 – Descriptive statistics 1
03	12 th October	C03 – Descriptive statistics 2
04	19 th October	C04 – Probabilities
05	26 th November	C05 – Confidence intervals
06	2 th November	C06 – Inferential statistics 1
07	9 th November	C07 – Inferential statistics 2
08	16 th November	C08 – Inferential statistics 3
09	23 th November	C09 – Inferential statistics 4
10	30 th December	C10 – Inferential statistics 5
11	7 th December	C11 – Inferential statistics 6
12	14 th December	C12 – Medical Informatics 1
13	11 th January	C13 – Medical Informatics 2
14	18 th January	C14 – Review

Bibliography

- Sorana BOLBOACĂ, Horațiu COLOSI, Tudor DRUGAN, Andrei ACHIMAȘ, Ștefan ȚIGAN, **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
 - Review, Practical part of the Exam example
 - Practical part of the exam

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



Department of Medical Informatics and Biostatitics

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

PRESENTATION ▾

EDUCATION ▾

RESEARCH

INFORMATION ▾



Site:

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Medical Research Methodology - General Medicine, Year 2

Children categories



Administrative issues

[View items...](#)



Lectures

[View items...](#)



Practical activities

[View items...](#)

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)

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- **Compulsory to follow request**

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• **Compulsory to follow request**

• Hints

Practical activity 1

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• **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 3 absences
 - Motivation or
 - without motivation (maximum 1)
 - possible payment (read the regulations)
 - if >3 absences (read the regulation)
 - **Recuperation**
 - 18th December 2026 at 15:30-17
 - 15th January 2027 at 15:30-17
- ! All absences (if any) must be made up

Regulations

- **Exemption from the practical part of the exam !!!**
- Students who
 - Didn't recuperate all the absences
 - Have more than 3 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**
 - **Maximum 3 times / year**
- Winter session
- Re-examination I session
 - 12th July 2027 – 16th July 2027
- Re-examination II session
 - 13th September 2027 – 17th September 2027

Evaluation

Type of learning activity	Assessment criteria	Assessment methods	Weight in final grade
Lecture	Correctness of answers to multiple responses question; Ability to synthesize and integrate knowledge from the taught topics.	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.	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 necessary **formulas**

you may receive an additional max 3 bonus points for your responses to quiz 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 !

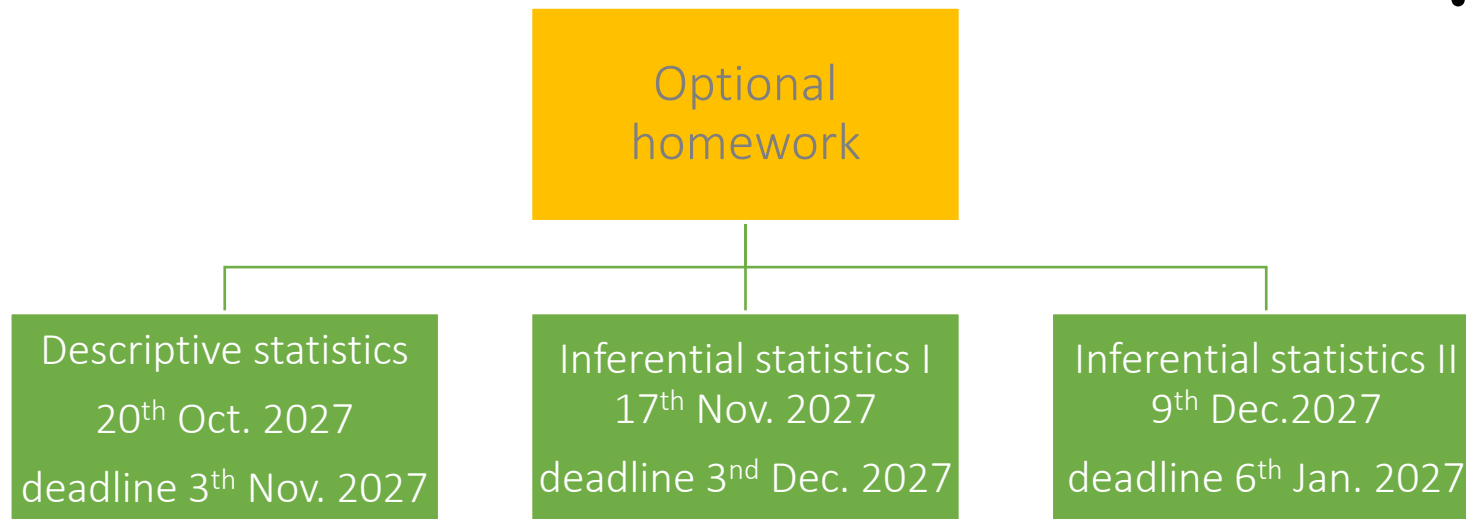
Final Mark

- If the student obtained
 - minimum 5 at practical part of the exam
 - respectively minimum 5 at theoretical part of the exam – (**13.7 points from 35 maximum**)
- The final mark will be computed

Final Mark

- Weighted mean
 - Theoretic part of the exam - 70%
 - Practical part of the exam - 30%
 - Weighted mean = $0.70 \times \text{theoretic exam mark} + 0.30 \times \text{practical exam mark}$
- If final mark < 10 , but greater than 5
 - Final mark = weighted mean + $0.2 \times \text{optional homework}$

Optional homework:



- deadlines!!!
- If you obtain minimum 5 at the submitted (quiz in Teams) homework
 - Final mark = weighted mean + $0.2 \times \text{no. of optional homework}$

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RESEARCH

INFORMATION 

Informatics



Methodology



Practical activities

Practical Activity 01 - Organizational Measures

Practical Activity 02: Formulas and Functions

Practical Activity 03 - Descriptive statistics for qualitative variable

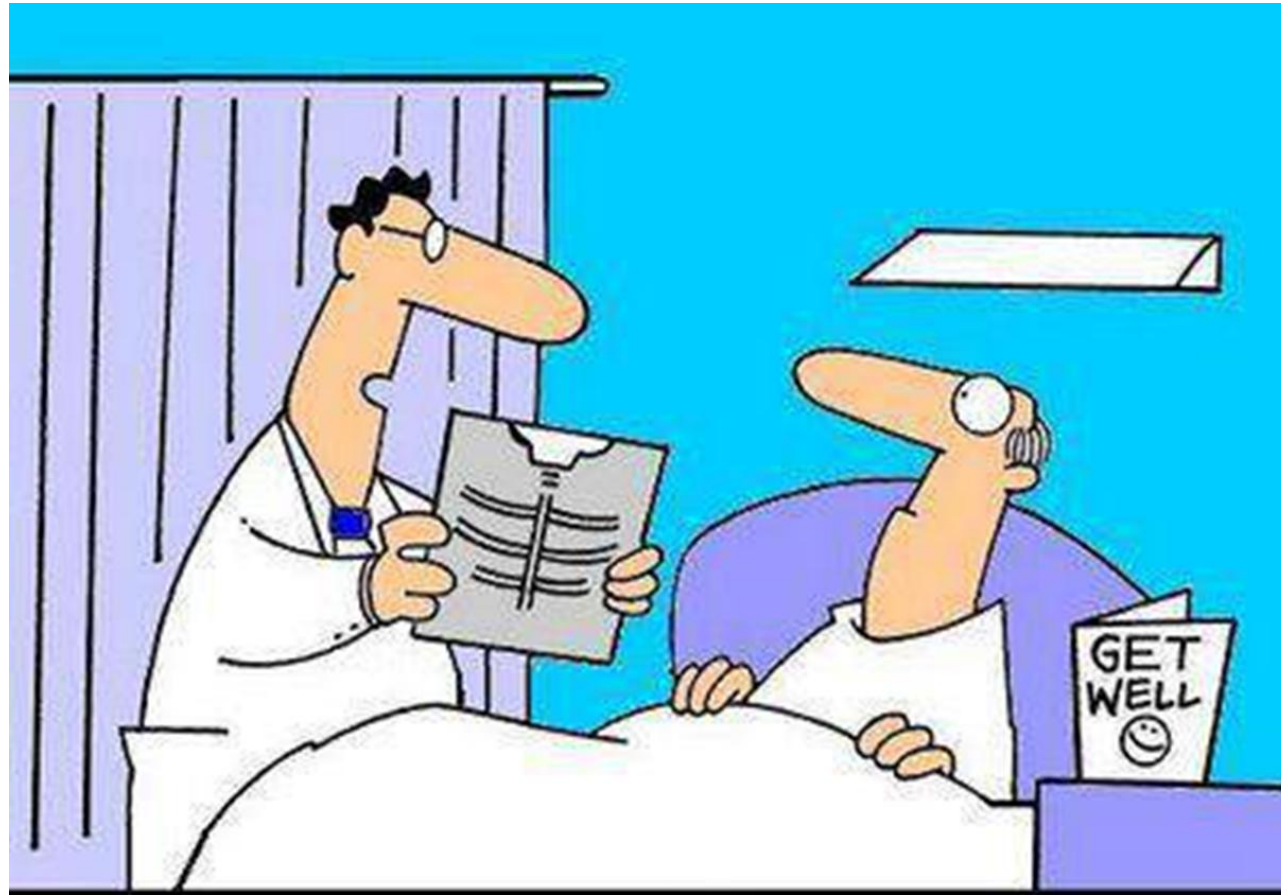
Practical Activity 04 - Descriptive statistics for quantitative variable

Practical activity 04 bis - Homework 1 - for lecture

Practical activity 05 - Probabilities

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 3 absences at PA
 - All made-up (with medical motivation, payment an additional 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!