

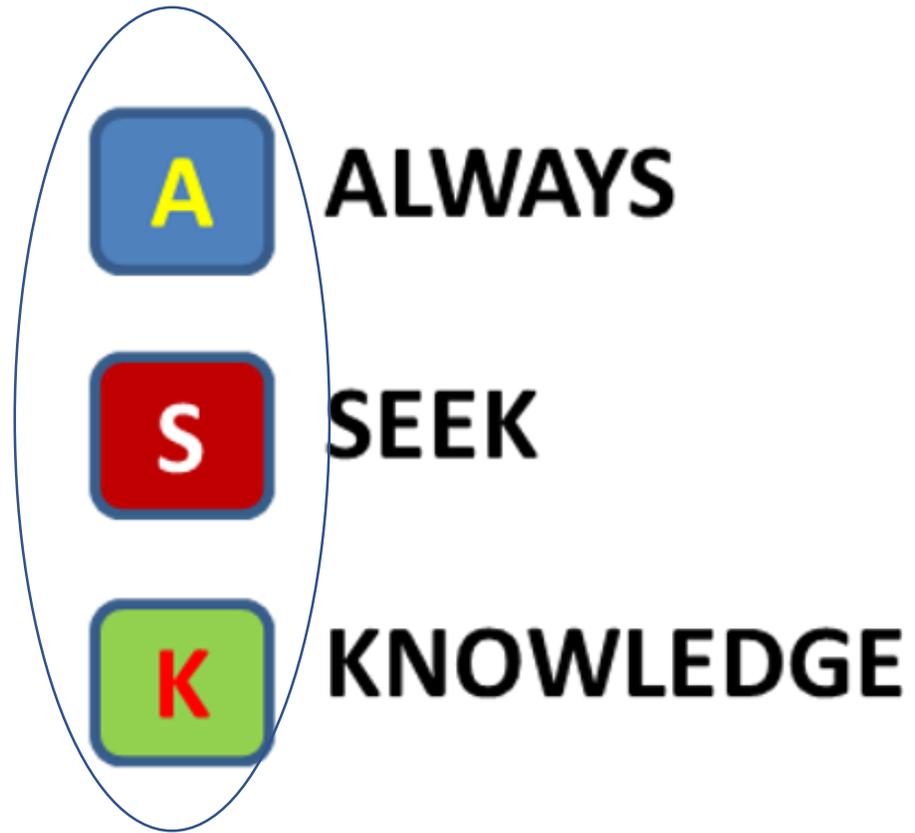
The image is a digital-themed background. It features a blue-tinted globe of the Earth on the left side. The foreground is dominated by a perspective view of a grid of binary code (0s and 1s) that recedes into the distance. On the right side, there are glowing, curved lines and a bright light source that creates a lens flare effect, suggesting data flow or connectivity. The overall color palette is various shades of blue, from deep navy to bright cyan.

Aim: Introduction

# Bondor Cosmina-Ioana

- Assistant professor (Coferențiar)
- Contact:
  - email [cbondor@umfcluj.ro](mailto:cbondor@umfcluj.ro)
  - Teams chat: Bondor Cosmina Ioana
- [My academic profile](#)

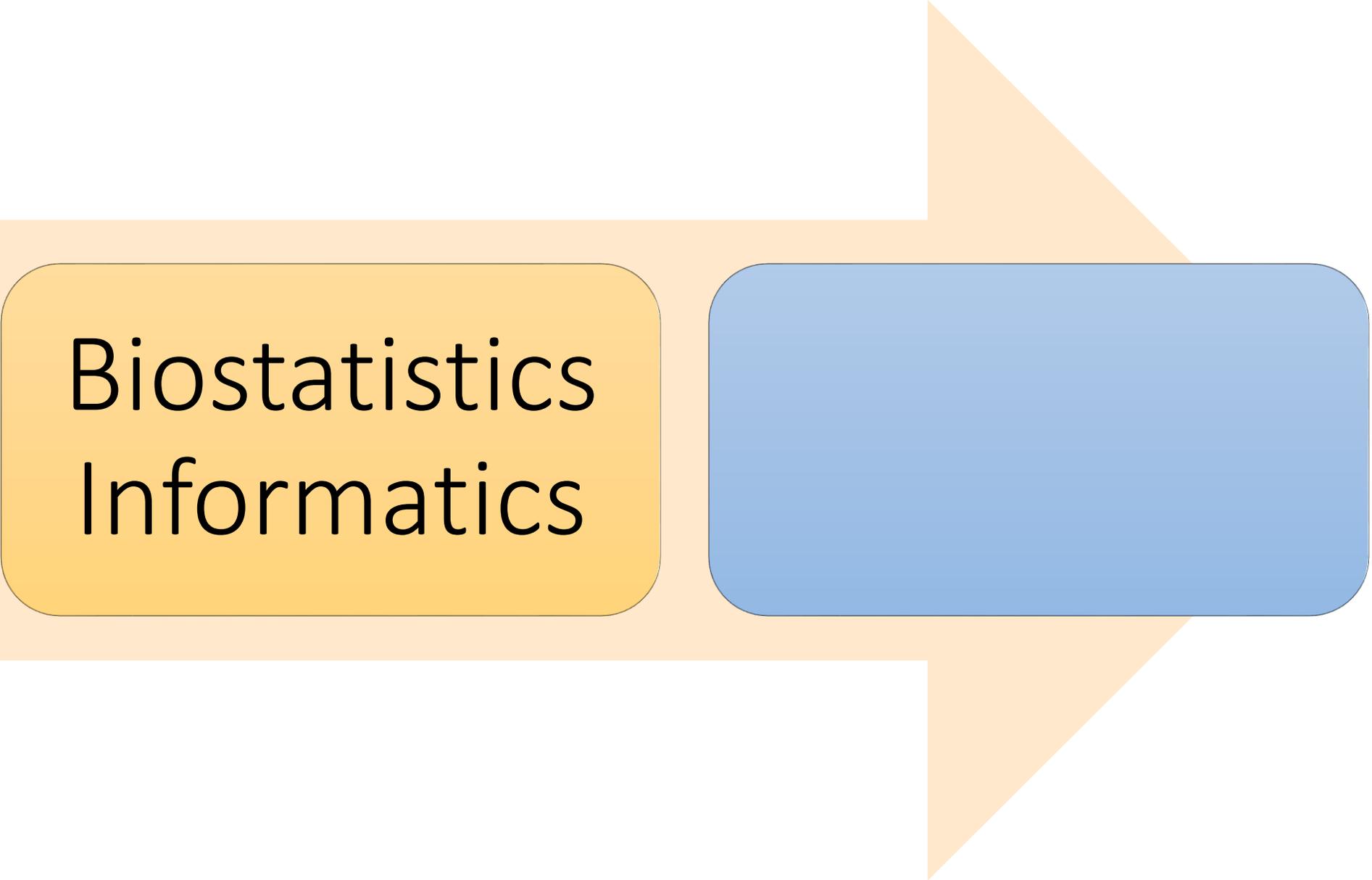




- **ASK** - always ask, anytime ask

- I will try to answer

What is the name  
of this lecture?



Biostatistics  
Informatics

Biostatistics  
Informatics

Medical

Biostatistics  
Informatics

Medical

Medical  
Biostatistics -  
Medical  
Informatics

Biostatistics  
Informatics

Medical

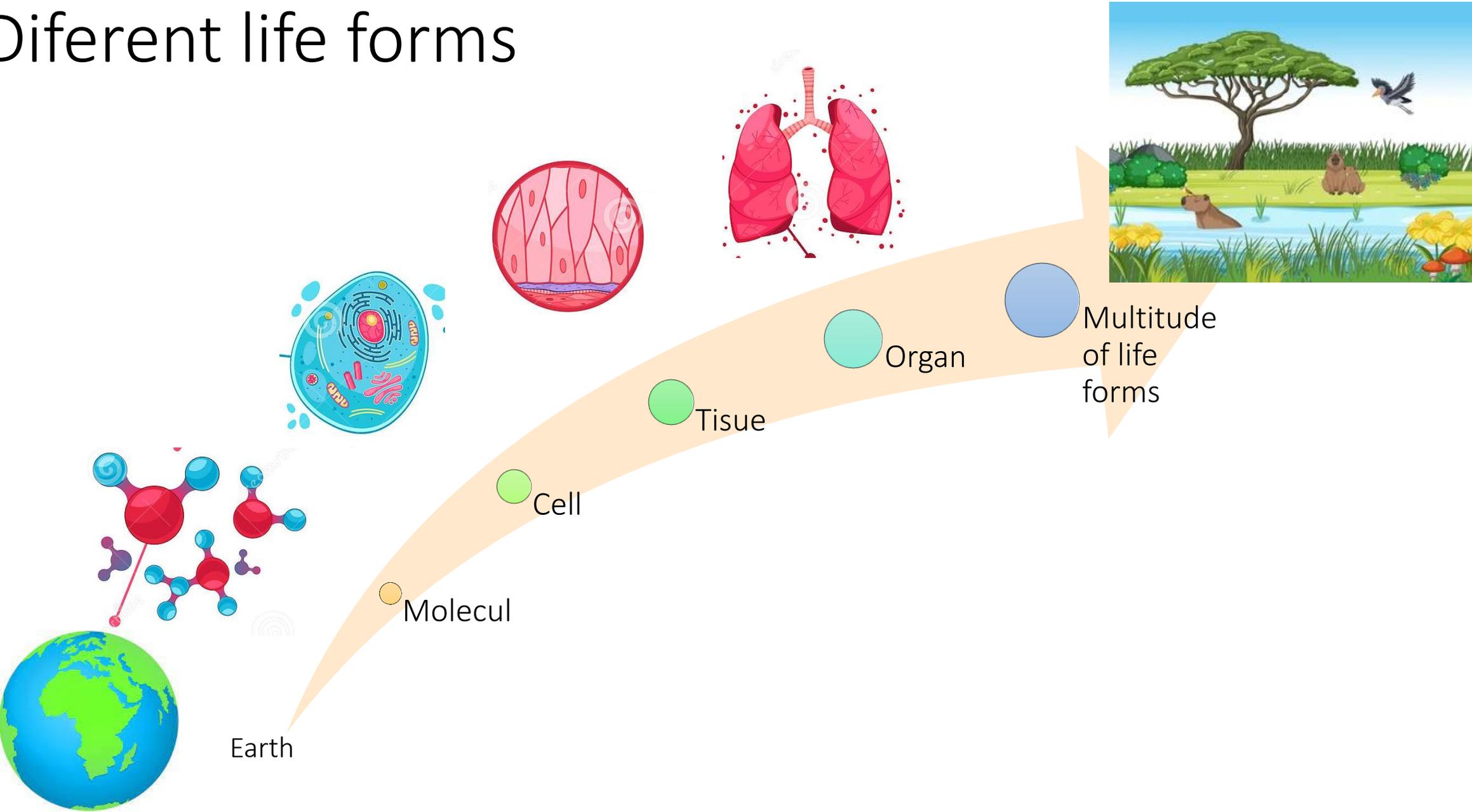
Medical  
Biostatistics  
Medical  
Informatics

**Biostatistics  
and Medical  
Informatics**

Why on Earth we should do this discipline?



# Diferent life forms



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



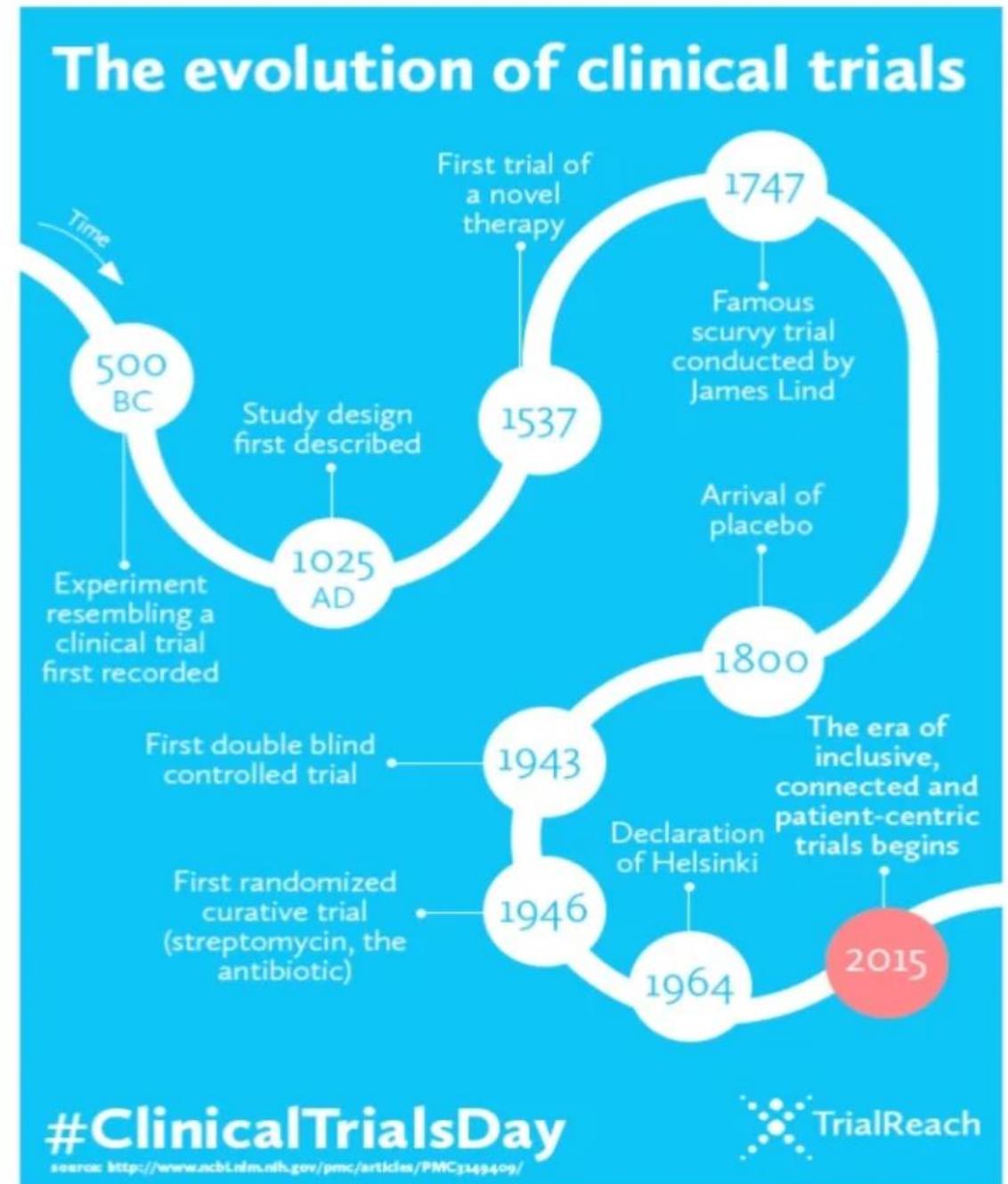
FAQ

... but

- Treat **some** disease
- Correct diagnostic **sometime**
- **Sometime** to predict the result

How did we get here?

# Medical research



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  $\geq 16$  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:

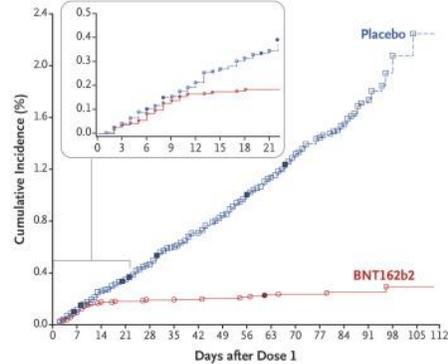
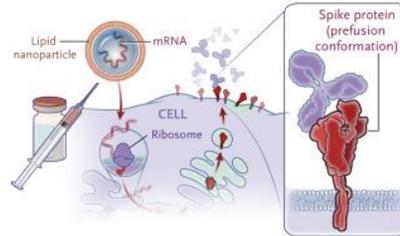
The vaccine showed some early protection 12 days after the first dose; 7 days after the second dose, 95% efficacy was observed.

### 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

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

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**RESULTS**

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**Efficacy:**

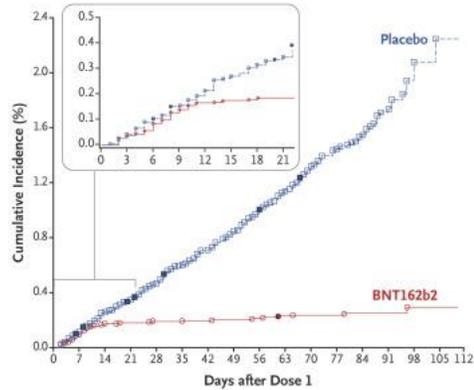
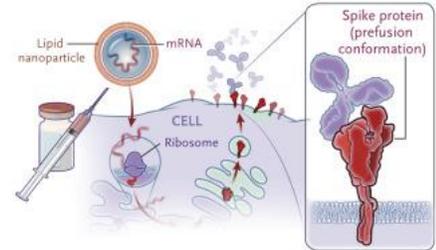
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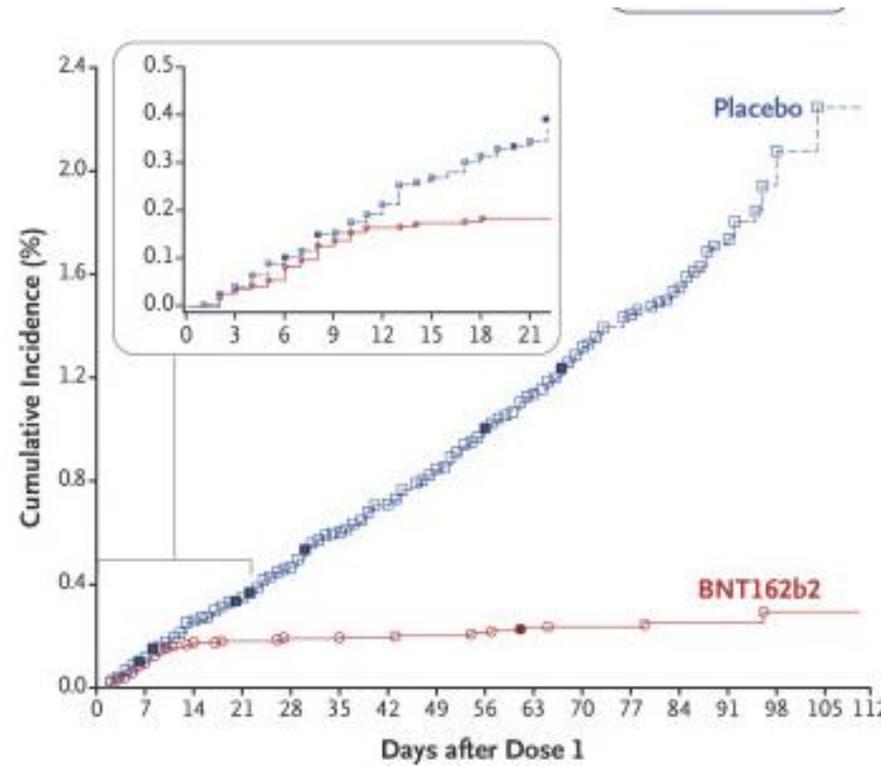


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# Pfizer vaccine anti – Covid-19



- What does this chart mean?

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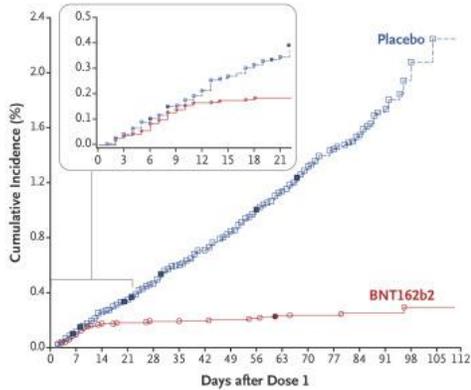
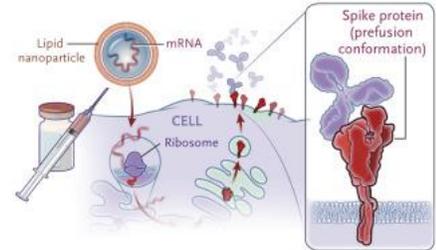
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**Vaccine efficacy of 95% (95% credible interval, 90.3–97.6%)**

• What does this mean?

Medical research is  
based on statistics

# Objectives

- The student should understand
  - Published articles
  - Medical research
- The student should know
  - Where to get the information
  - How to search for medical information

First time...  
statistics



We will present for you - Release date (The movie)

Methodology of the  
research (February 2025)

# Aim of this presentation:

## Lecture

General presentation

Objectives

Lecture content

## Exam

Theoretic

Practic

Homework

## Regulations

Didactical

Intern

Specific

# SEMESTER I

2nd October  
2023 – 22th  
December 2023

- Didactic activity
- 12 weeks

23th  
December  
2023 – 7th  
January 2024

- Vacation
- 2 weeks

8th January  
2024 – 14th  
January 2024

- Didactic activity
- 1 weeks

15th January  
2024 – 19th  
January 2024

- Didactic activity
- Practical exam
- 1 week

22th January  
2024 – 16th  
February 2024

- Exam sesion
- 4 weeks

19th February  
2024 – 23th  
February 2024

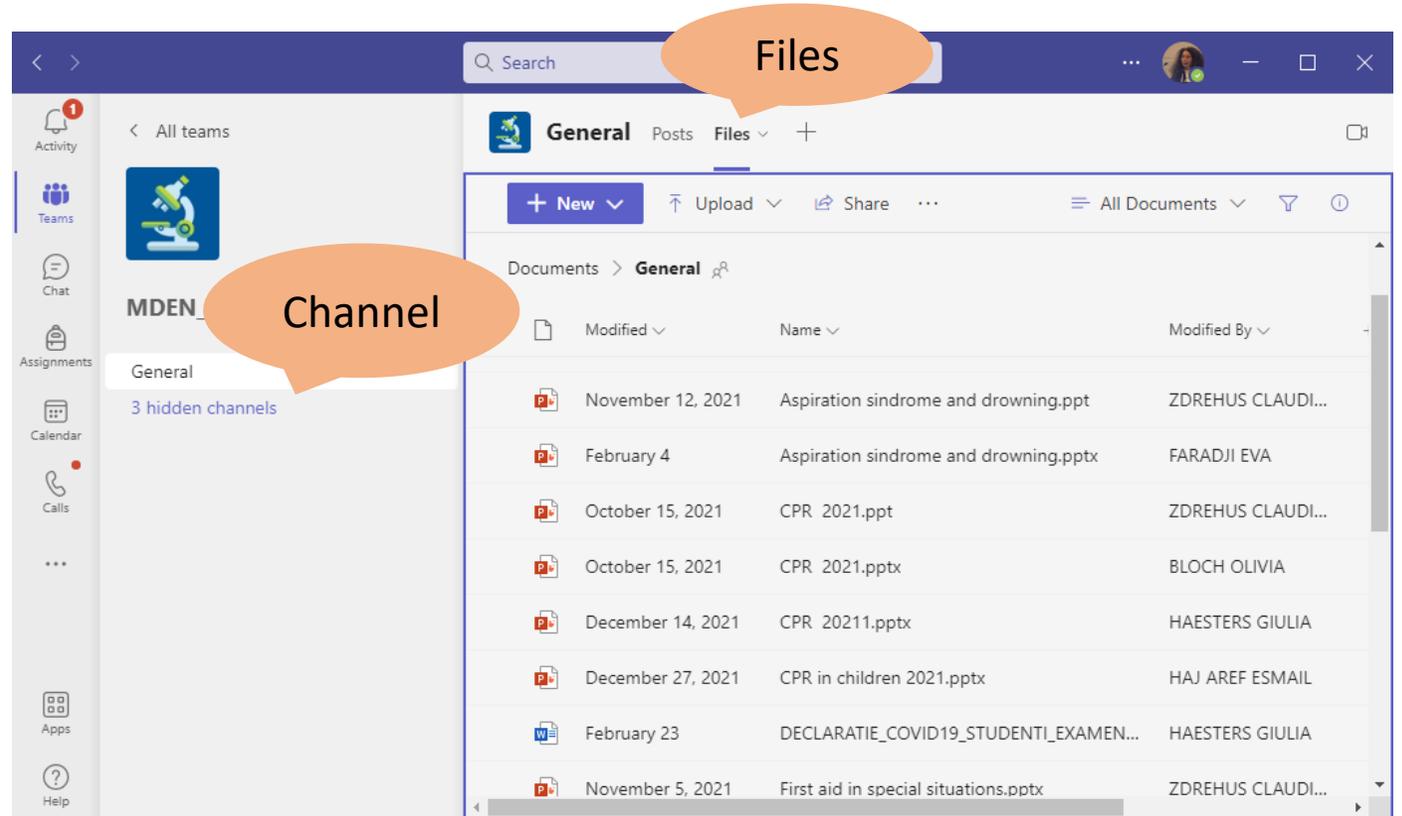
- Vacation
- 1 week

## Didactic activity

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

Săptămâna	Data	Activitate curs
01	03rd October	C01 – Introduction
02	10th October	C02 – Descriptive statistics 1
03	17 th October	C03 – Descriptive statistics 2
04	24th October	C04 – Descriptive statistics 3
05	31th November	C05 – Probabilities
06	7th November	C06 – Probabilities distribution. Sampling
07	14th November	C07 – Confidence intervals
08	21th November	C08 – Inferencial statistics 1
09	28th November	C09 – Medical Informatics 1
10	05th December	C10 – Inferencial statistics 2
11	12th December	C11 – Inferencial statistics 3
12	19th December	C12 – Inferencial statistics 4
13	9th January	C13 – Medical Informatics 2
14	16th January	C14 – Recapitulation

- Lectures will be posted in Teams in Files in Biostatistics and Medical Informatics channel



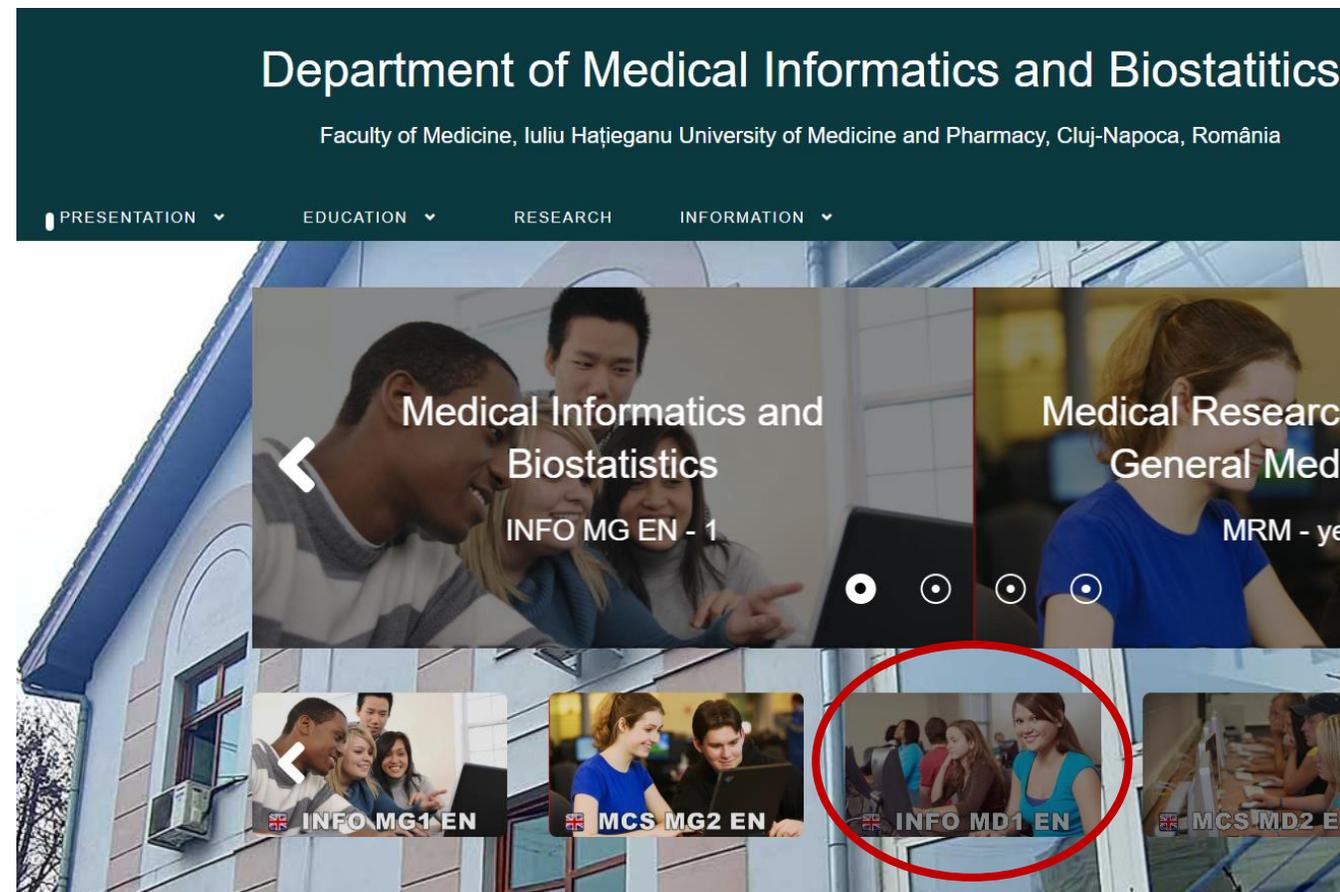
## Bibliography

- 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, any edition.

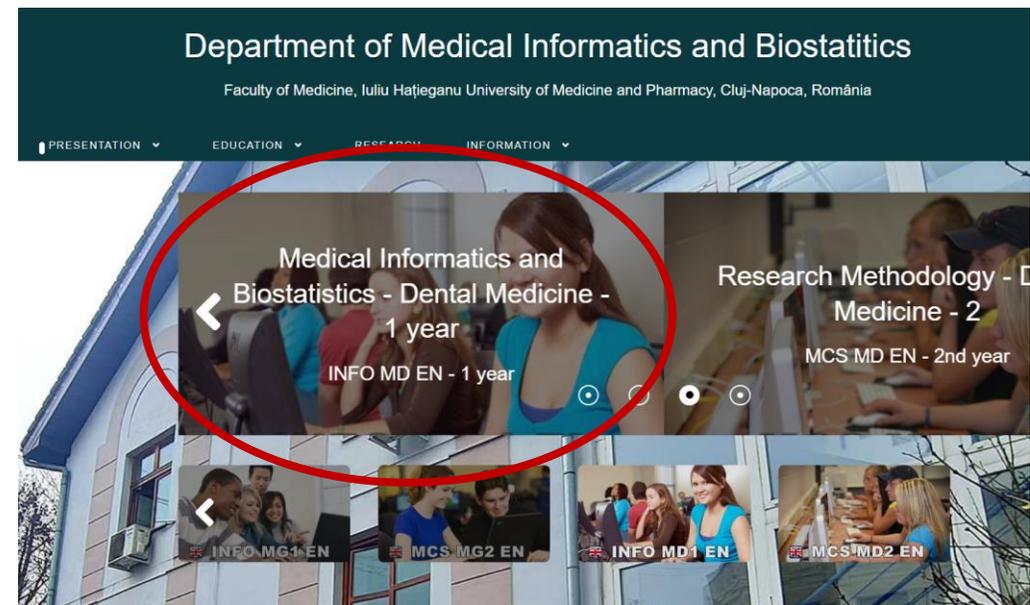
## Didactic activity

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

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



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



## Medical Research Methodology - General Medicine, Year 2

### Children categories



### Administrative issues

View items...



### Lectures

View items...



### Practical activities

View items...

# Practical activity 2

## 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)

# Practical activity 1

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- **Compulsory to follow request**

# Practical activity 1

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 LP1\_Hints\_Formulas\_and\_Functions.docx (20 Downloads) LP1\_optional\_Formula\_and\_Functions.doc (18 Downloads)

• **Compulsory to follow request**

• Hints

# Practical activity 1

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**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 (18 Downloads)  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 situation will be taken

# Regulation - student obligation

- **Practical activities**
- Minimum 100% attendance
  - The presence situation will be taken
- Maximum 3 absences
  - Medical motivation or with payment till 12 January 2024
  - Recuperation till 12 January 2024
- ! All 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 3 absences at LP
  - Suspended
    - see the internal rules
      - rules which will be presented at the LP

# 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
  - 9th July 2024 – 12th July 2024
- Re-examination II session
  - 16th July 2024 – 19th July 2024

# Evaluation

Activity type	Evaluation criteria	Evaluation methods	Weight of the final grade
<b>Theoretical</b> part of the exam	Consistent with educational objectives	In conformity with the university regulations	70%
<b>Practical</b> part of the exam	Consistent with educational objectives	In conformity with the university regulations	30%

Minimum mark = 5 at both exams

# Theoretical exam - 30 questions: 1 hour to respond

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 !**

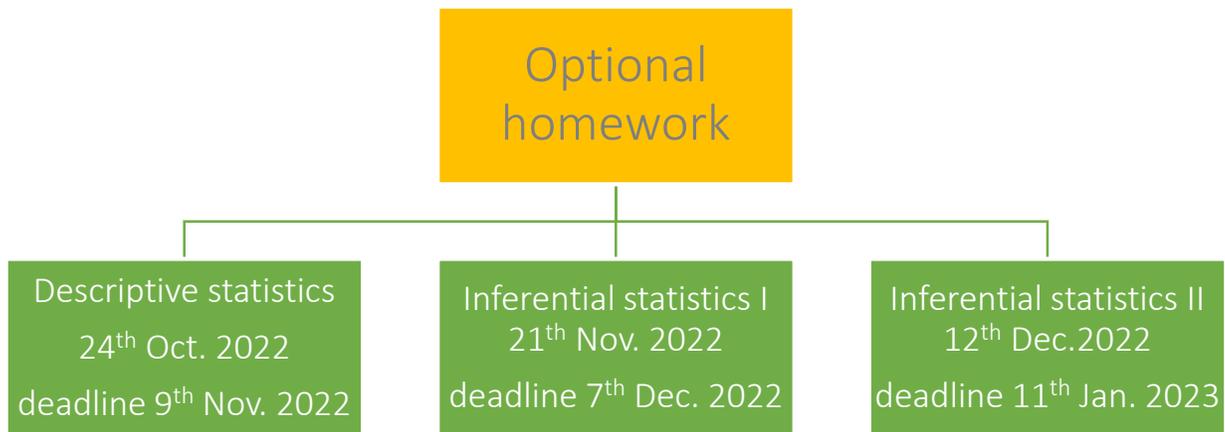
# Final Mark

- 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 =  $0.70 \times \text{theoretic exam mark} + 0.30 \times \text{practical exam mark}$
- If final mark < 10
  - Final mark = weighted mean +  $0.2 \times \text{optional homework}$

# Optional homework:



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



## 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**

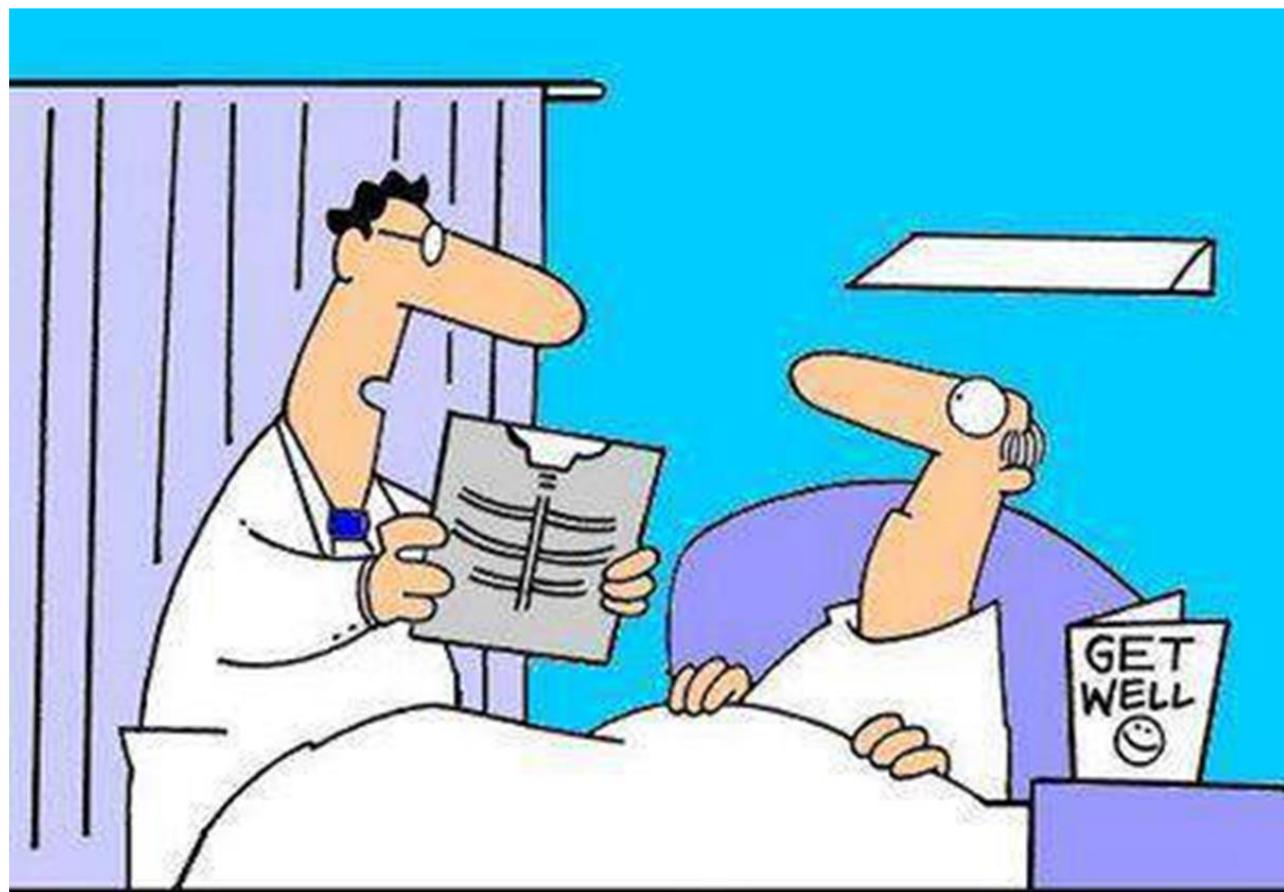
**Practical activity 04 bis - Homework 1 - for lecture**

**Practical activity 05 - Probabilities**

# Objectives of optional - supplementary work

- To help student to pass the exam
  - if no/week computer competencies --> doing the **supplementary work from practical activity** will help you
- try to understand what are you doing at LP (not only follow the requests and hints)
  - if you know how to make the supplementary work → you understand what you did at the LP
- homeworks from theoretical exam
  - similar to theoretical exam

- 14 LP – one each week
  - 75%-100% from compulsory activities must be done during each LP = presence at LP
  - <75% from compulsory activities during the LP = absence at LP
- Maximum 3 absences at LP
  - All made-up (with medical motivation, payment an additional fee)
- Practical exam in the last week during LP
- Minimum 5 at practical part of the exam --> pass -->
- --> minimum 70% attendance to lecture --> theoretical part of the exam --> minimum 5 at theoretical exam -->
- Done



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