Introduction

Péter Hegyi

Centre for Translational Medicine

p.hegyi@tm-centre.org

11th September, 2019

University of Pécs
Pécs

TRANSLATIONAL MEDICINE

taking discoveries for patients benefits

Q1 WHAT IS TRANSLATIONAL MEDICINE?

TRANSLATIONAL MEDICINE

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TRANSLATIONAL MEDICINE

HEALTH CARE

QUESTION

PRACTICE

SCIENCE

EDUCATION

BASIC SCIENCE PURE FUNDAMENTAL RESEARCH	APPLIED SCIENCE DEVELOP KNOWLEDE FOR PRACTICAL APPLICATION	CLINICAL SCIENCE PRACTICAL APPLICATION
DISCOVERING NEW MECHANISMS AND TARGETS	DEVELOPING NEW DRUGS AND INTERVENTIONS	UNDERSTANDING SAFTEY AND EFFECTIVENESS
MOLECULAR BIOLOGY CELLULAR IMAGING PHYSIOLOGY	PHARMACOLOGY DEVICE D. INTERVENTIONAL D.	META-ANALYSIS INTERVENTIONAL CT OBSERVATIONAL CT PROSPECTIVE DA RETROSPECTIVE DA

TRANSZLÁCIÓS MEDICINA Pécs

EDUCATION

GRADUATE AND POSTGRADUATE EDUCATION, PATIENT CLUBS DISSEMINATION OF INFORMATION

- FOR PROFESSIONALS
- FOR NON-PROFESSIONALS

SCEINTIFIC PUBLICATION

KNOWLEDGE PUBLICATION

KNOWLEDGE

TRANSLATIONAL MEDICINE

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TM TRANSLATIONAL MEDICINE

HEALTH CARE

TM Fejér County Szent György University Teaching Hospital
Centre for TRANSLATIONAL MEDICINE

CONSULTANT

PhD STUDENTS

RESIDENT

DATA MANAGERS

NURSE

PATIENTS COORDINATOR

DISCIPLINES

ER
LAB MEDICINE
RADIOLOGY
ICU
SURGERY

TRANSLATIONAL MEDICINE

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TM TRANSLATIONAL MEDICINE

DATA MANAGER

PhD STUDENT

PATIENTS' CLUB LEADER

PATIENTS COORDINATOR

NURSES

RESIDENT

CONSULTANTS

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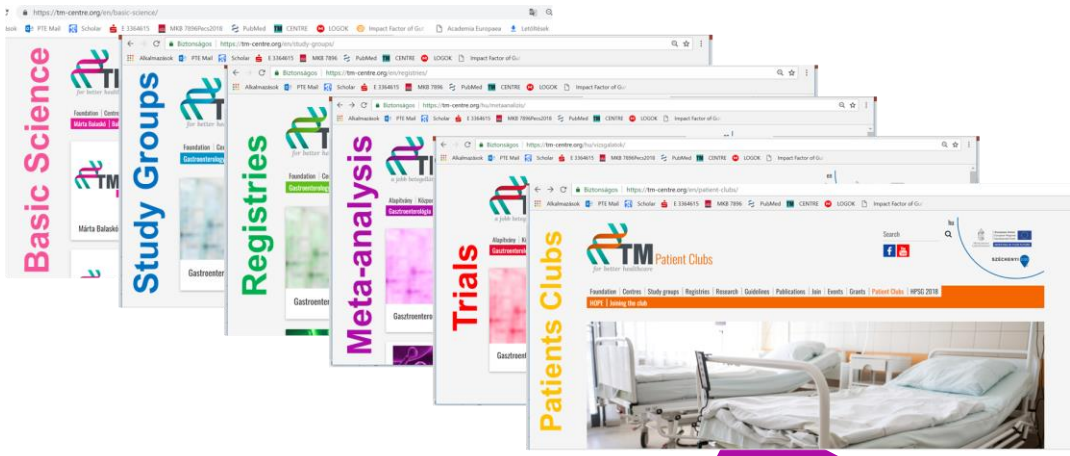
WHAT WE KNOW

University of Pécs
Centre for TRANSLATIONAL MEDICINE

WHAT WE DON'T KNOW

University of Pécs
Centre for TRANSLATIONAL MEDICINE



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TRANSLATIONAL MEDICINE

HEALTHCARE

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EDUCATION

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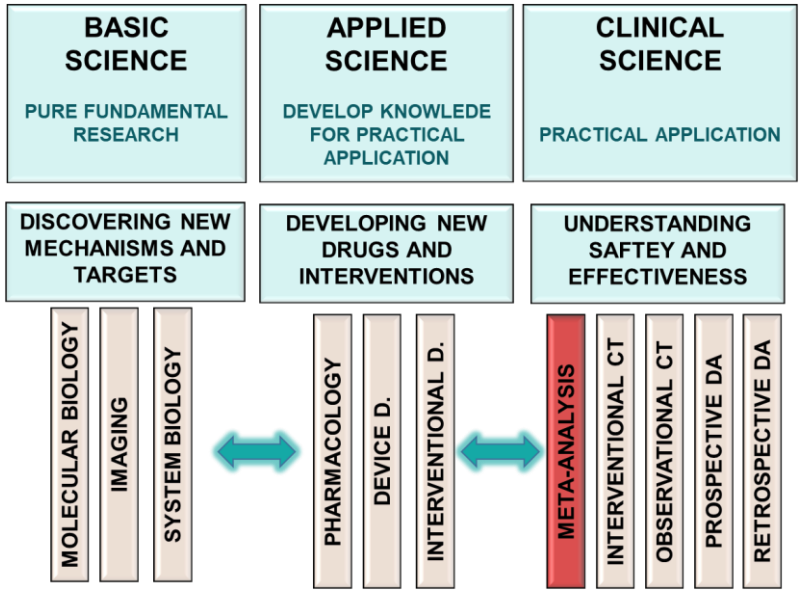
KNOWLEDGE PUBLICATION

KNOWLEDGE

Q2 WHAT IS TRANSLATIONAL SCIENCE?



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UNKNOWN → KNOWN

QUESTION

HYPOTHESIS

METHODOLOGY

COLLECTING DATA

ANALYSES

ANSWERS

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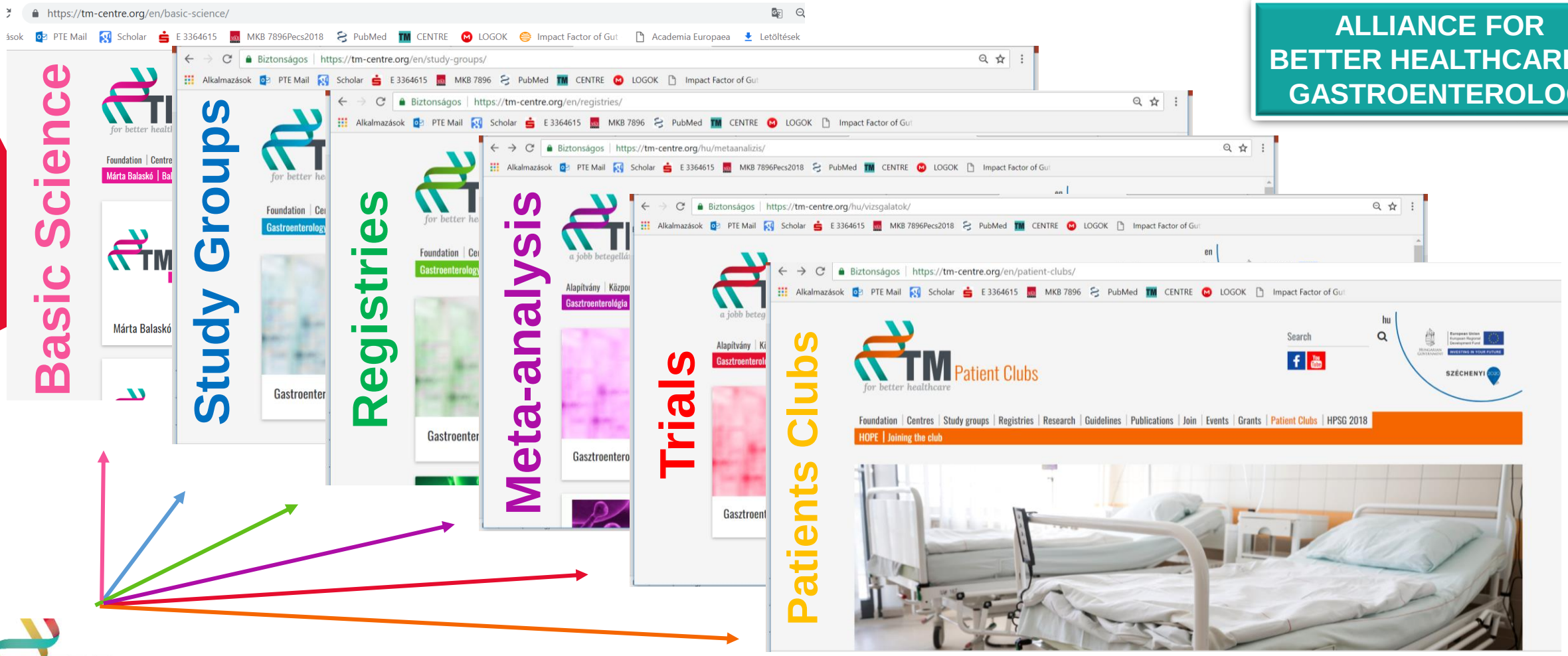
HUNGARIAN PANCREATIC STUDY GROUP

TRANSLATIONAL MEDICINE

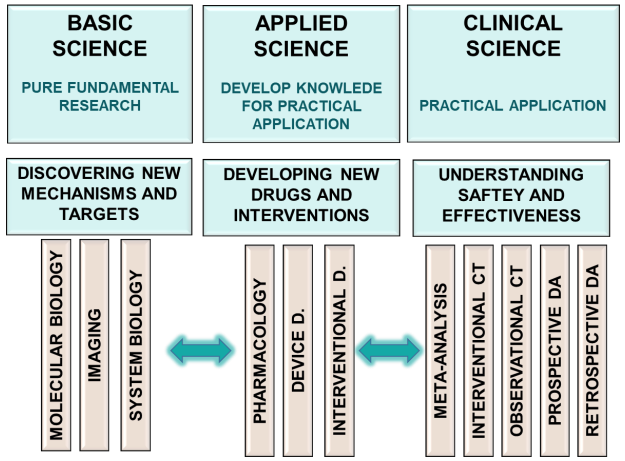
ALLIANCE FOR BETTER HEALTHCARE IN GASTROENTEROLOGY



University of Pécs Centre for TRANSLATIONAL MEDICINE

www.tm-centre.org

Q3 WHICH METHODOLOGIES ARE USUALLY TEACHED AND USED IN HUNGARY?



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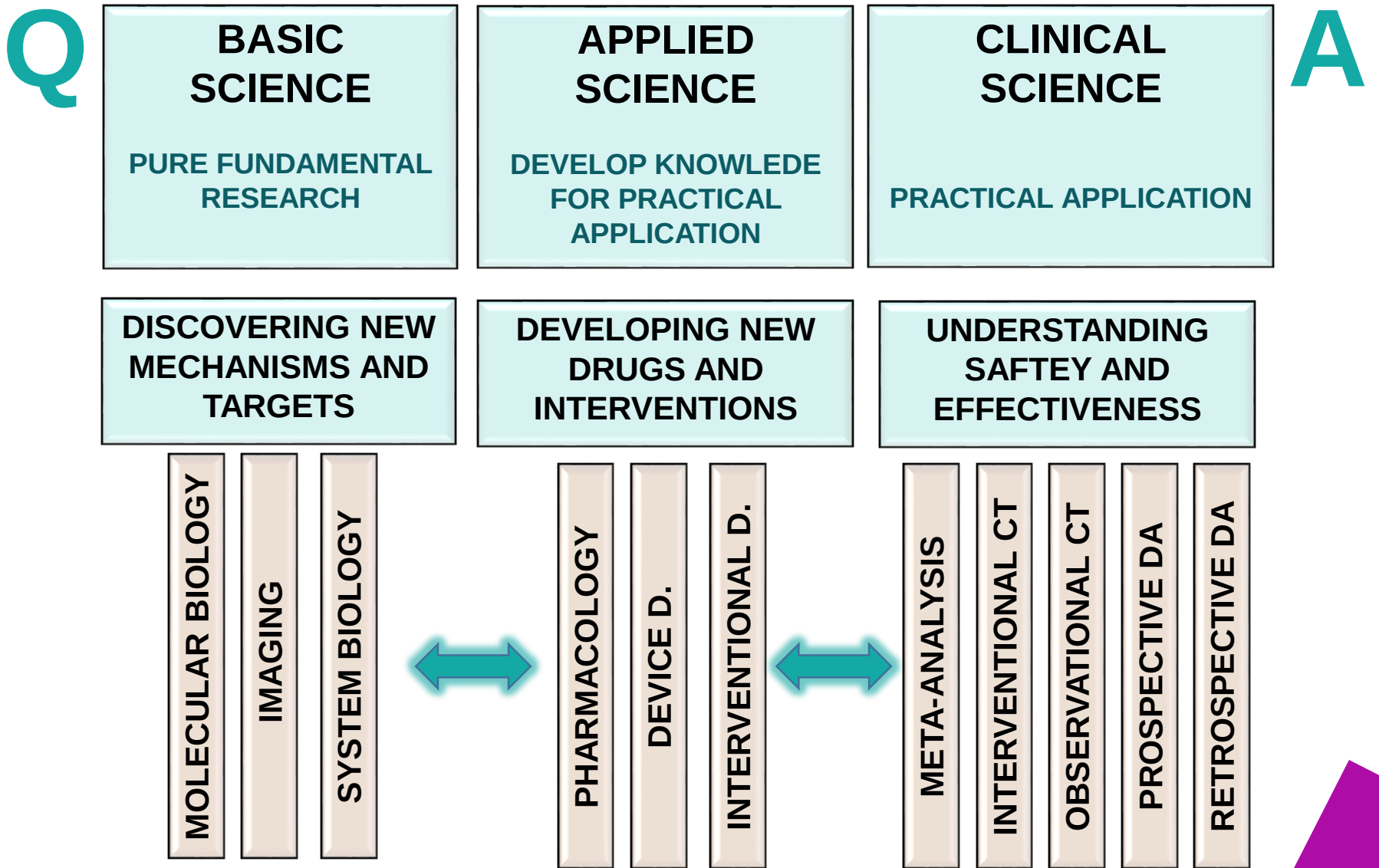

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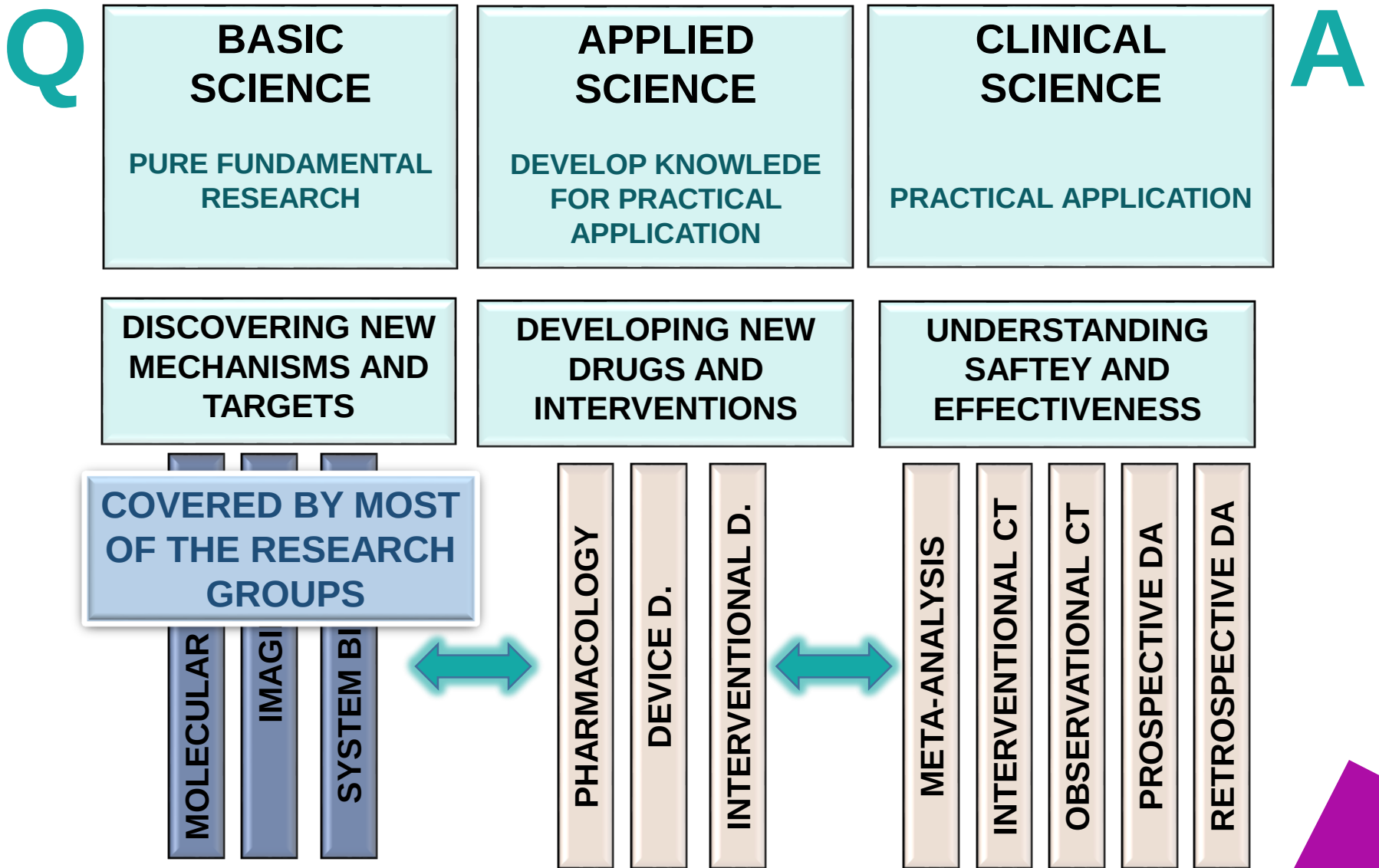

TRANSLATIONAL MEDICINE

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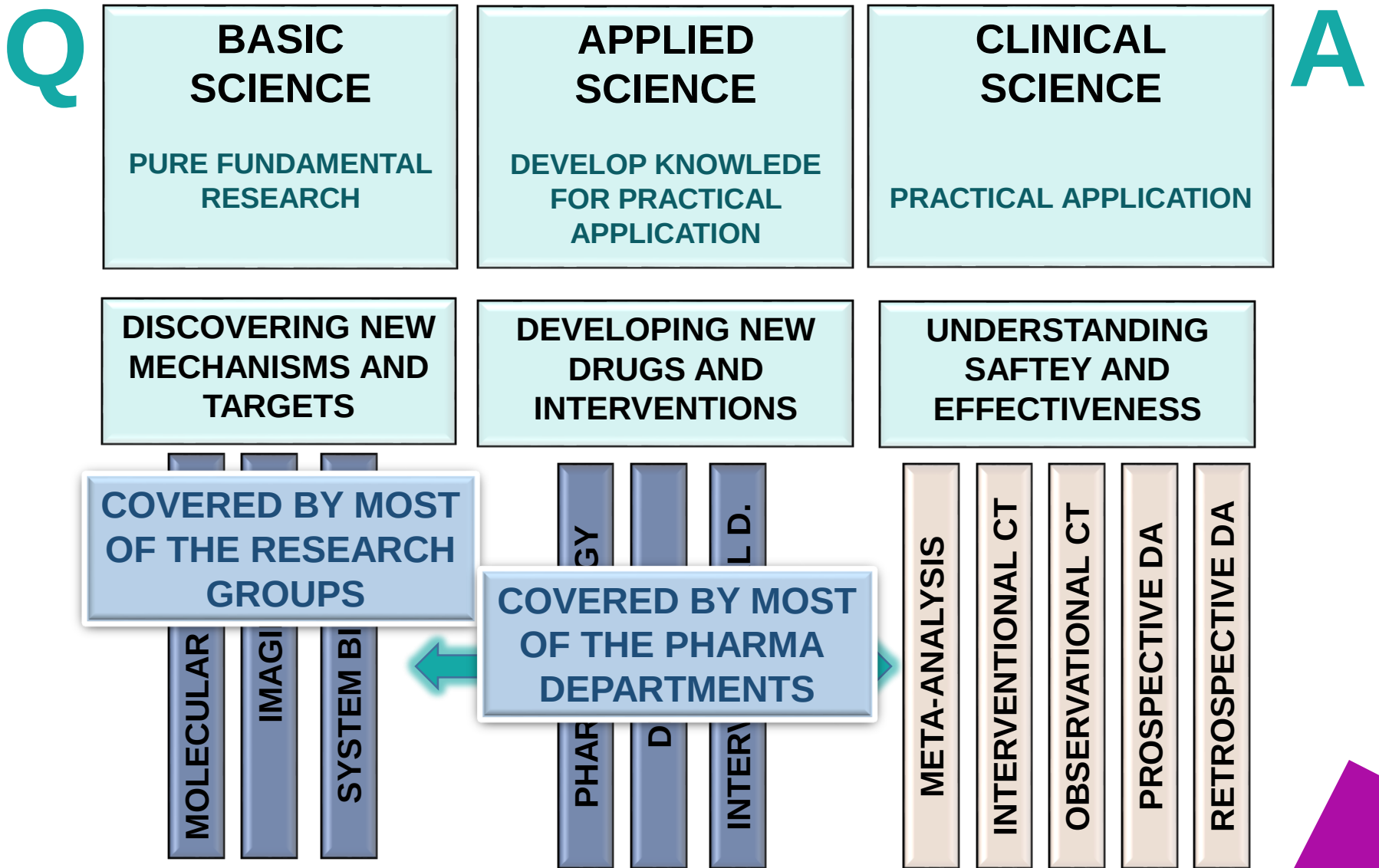

TRANSLATIONAL MEDICINE

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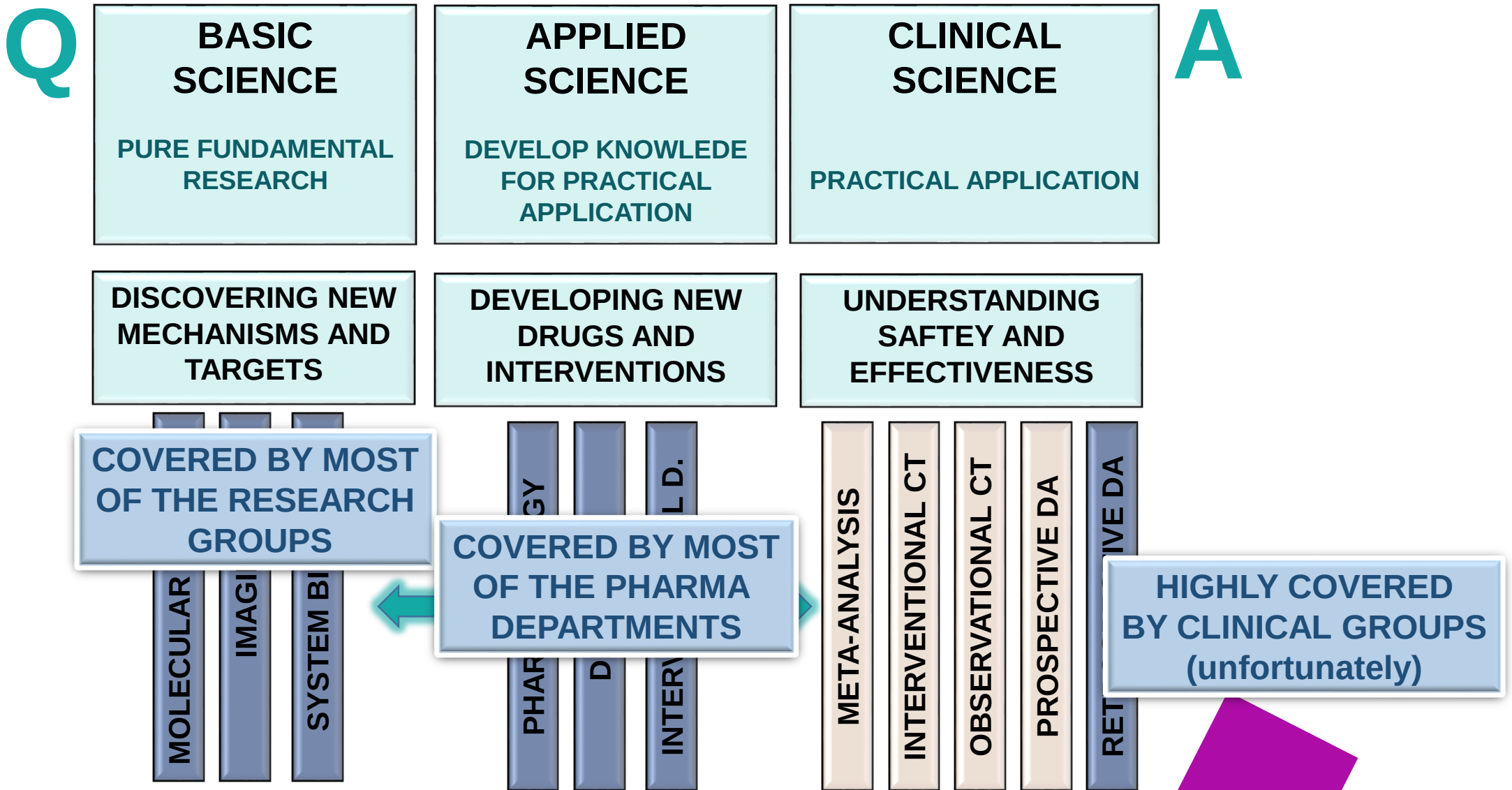

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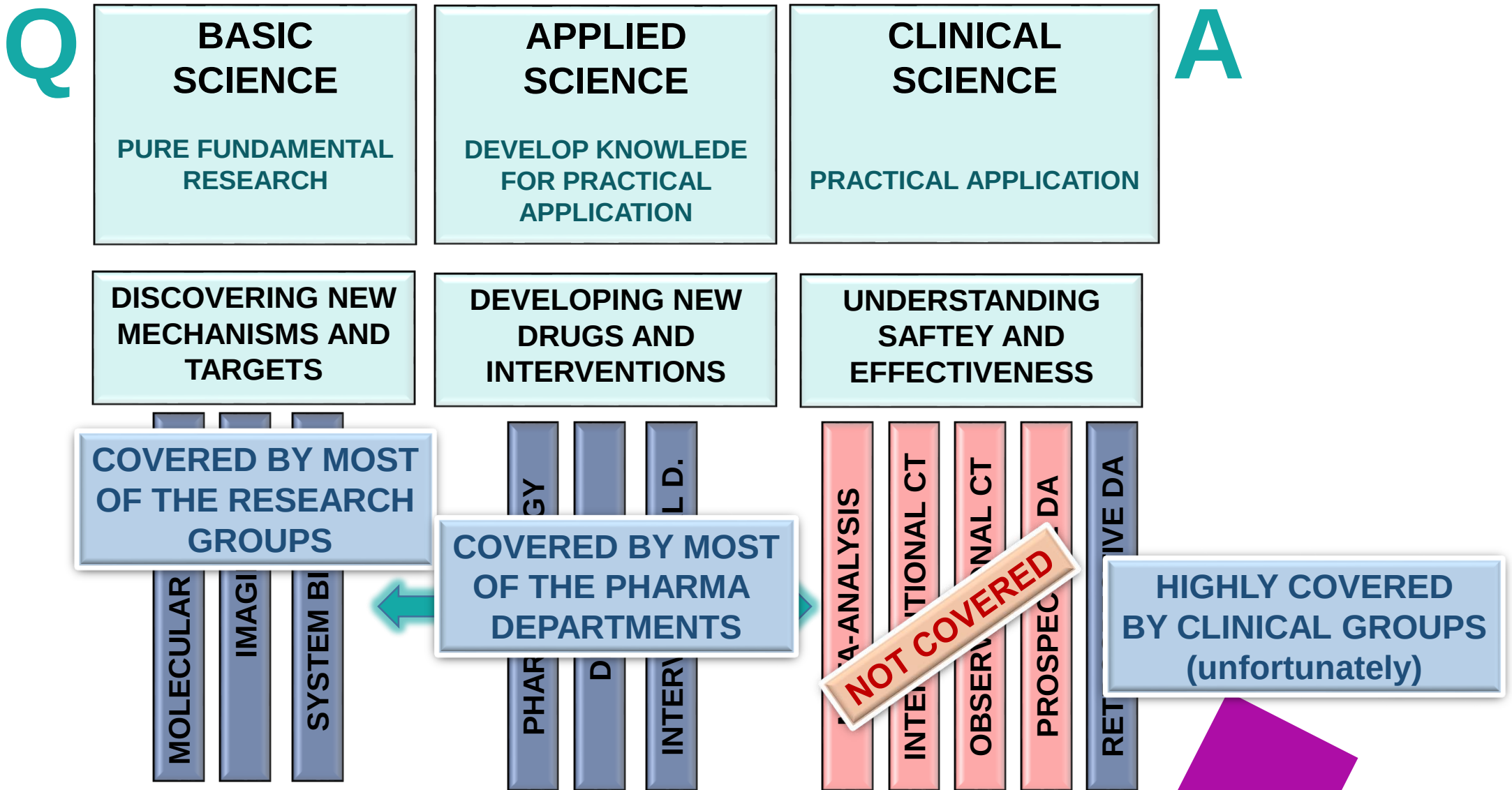

Q4 WHAT ARE THE OTHER DIFFICULTIES?

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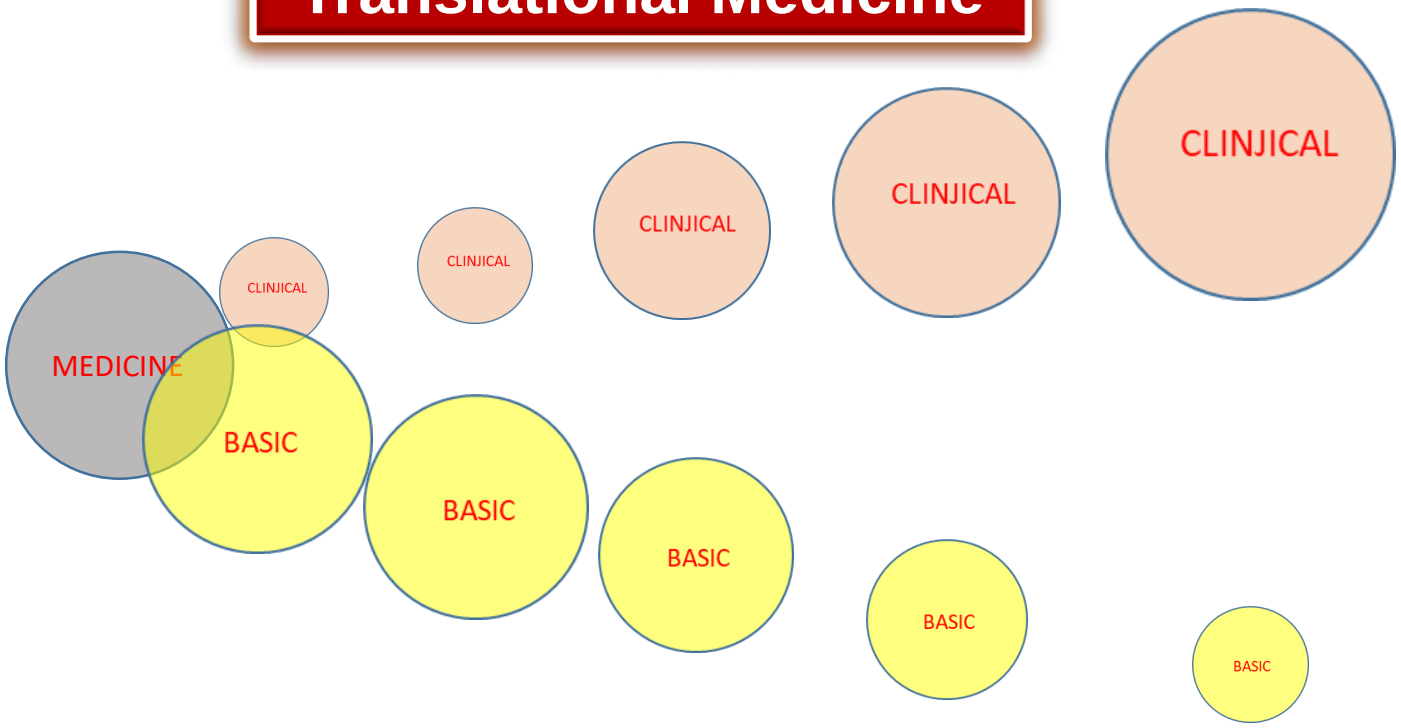
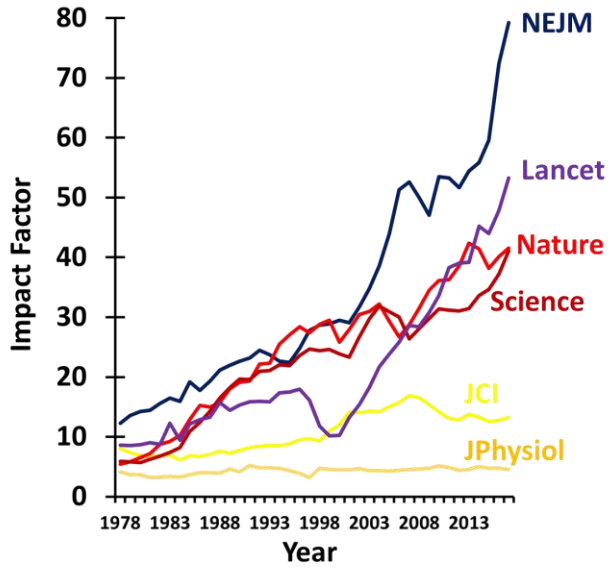
Translational Medicine





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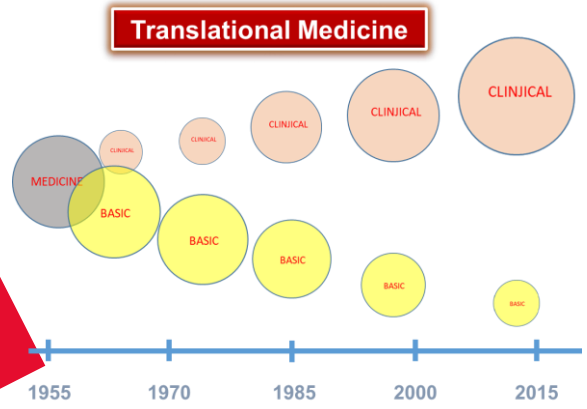
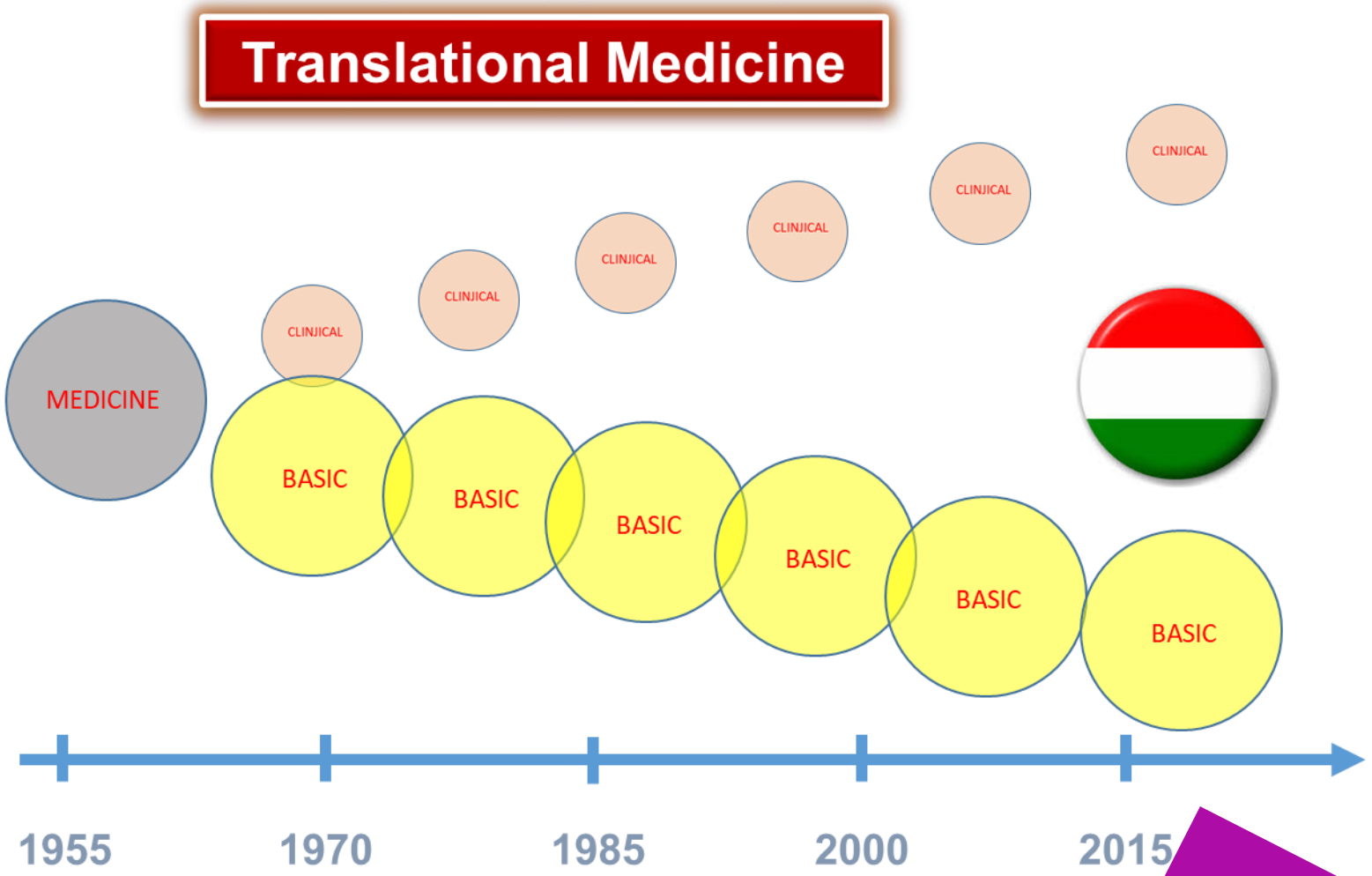
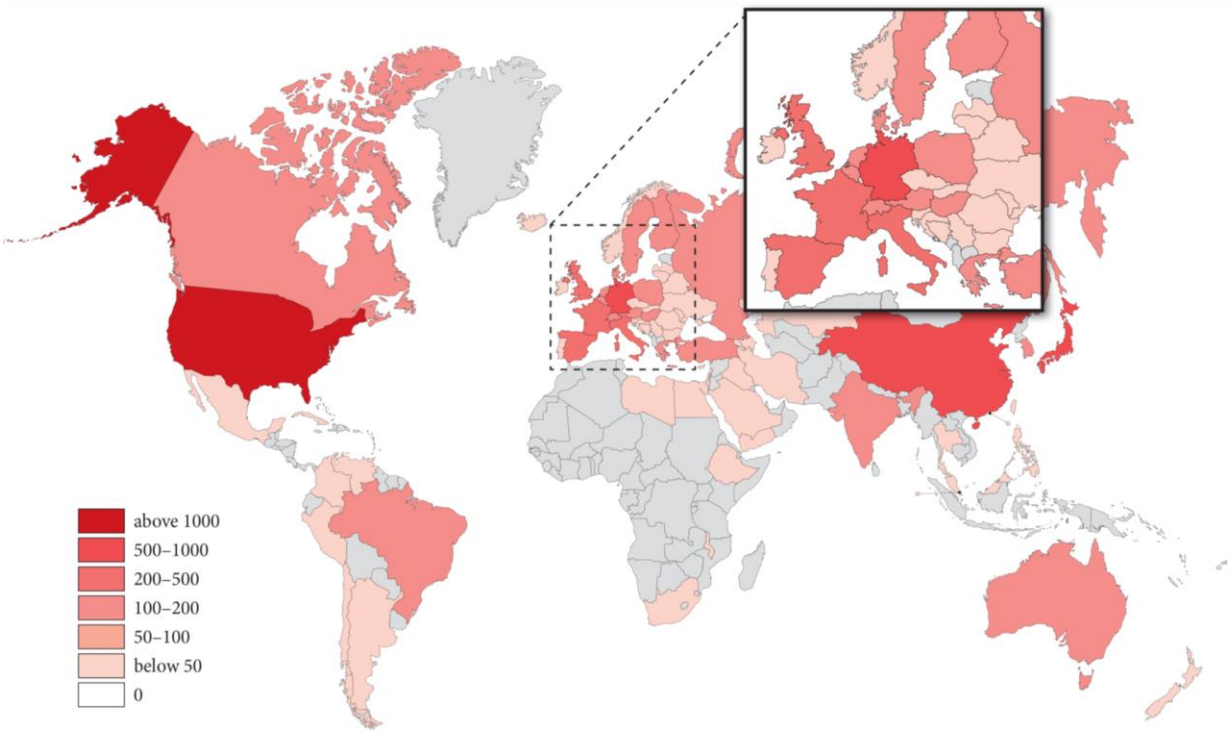




PUBLISHED ARTICLES/COUNTRIES



No	Countries	All articles
1	USA	2128
2	Germany	827
3	Japan	808
4	China	506
5	Italy	462
6	UK	382
7	France	253
8	Spain	217
9	Sweden	175
10	The Netherlands	174

Szentesi A et al. Analysis of research activity in gastro-enterology: Pancreatitis is in real danger. *PLOS One* 2016

S/COUNTRIES

No	Countries	All registered trials
1	USA	122
2	Germany	69
3	Japan	53
4	Italy	48
5	UK	36
6	The Netherlands	32
7	France	29
8	Canada	18
9	Hungary	16
10	Belgium	15

Szentesi A et al. Analysis of research activity in gastro-enterology: Pancreatitis is in real danger. *PLOS One* 2016

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PhD Theseis

QUALITY

MIRROR

2008-2018

PhD degree

n=188

BASIC SCI

ARTICLES

n=431

CLINICAL SCI

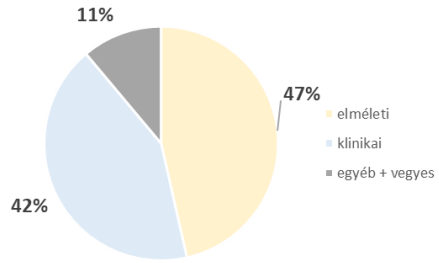
ARTICLES

n=133

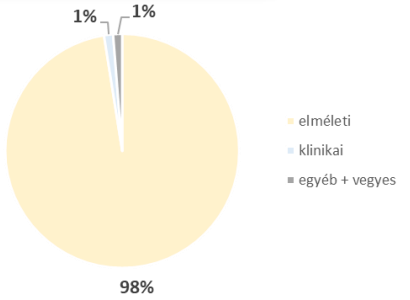
Intézet	DB	Téma	Darabszám
klinikai	99	elméleti	46
		klinikai	42
		egyéb + vegyes	11
elméleti	80	elméleti	78
		klinikai	1
		egyéb + vegyes	1
vegyes	9	elméleti	9
ÖSSZESEN	188		

CATHEGORIES

CLINICAL



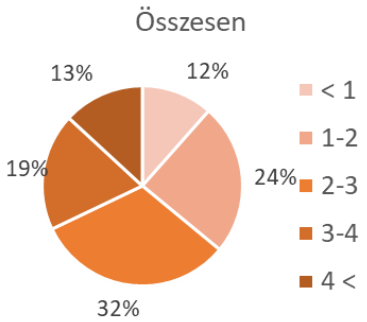
BASIC

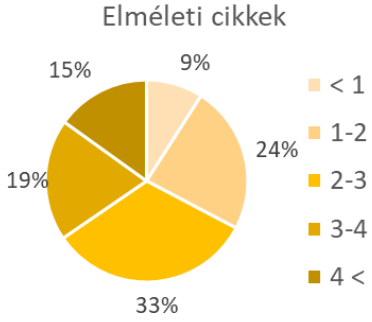


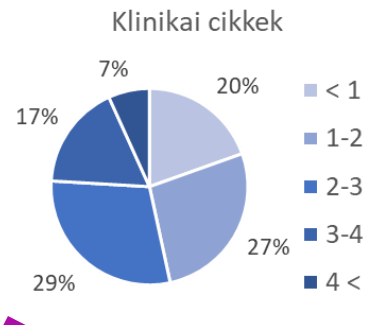
TOTAL IF

TÉMA	össz IF	IF/cikk	max IF
Elméleti	1196,236	2,78	20,98
Klinikai	292,924	2,2	6,462
Egyéb + Vegyes	78,809	2,13	4,16
Összesen	**1567,969**	**2,61**	**20,98**

DETAILED IF







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CLINICAL SCIENCES

QUALITY

MIRROR

REGSITRATION

3.6%

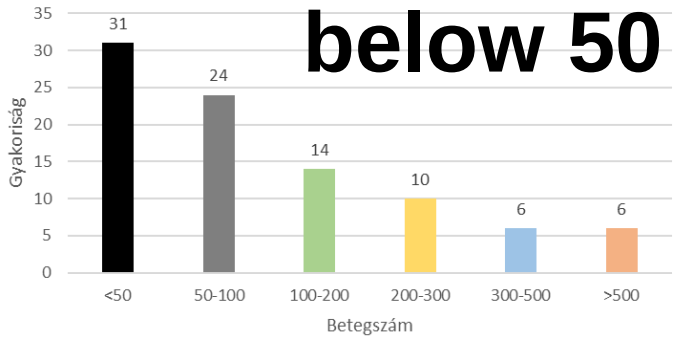
n=53

SAMPLE SIZE CALCULATION

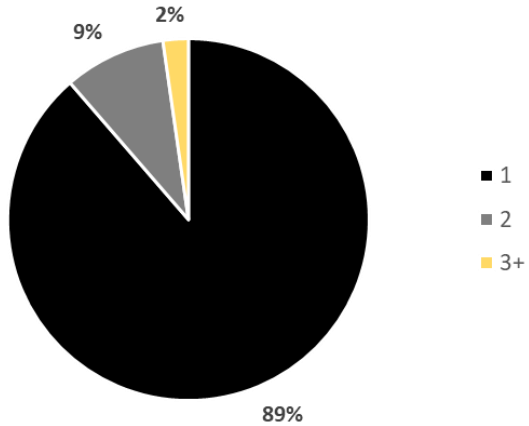
0%

n=53

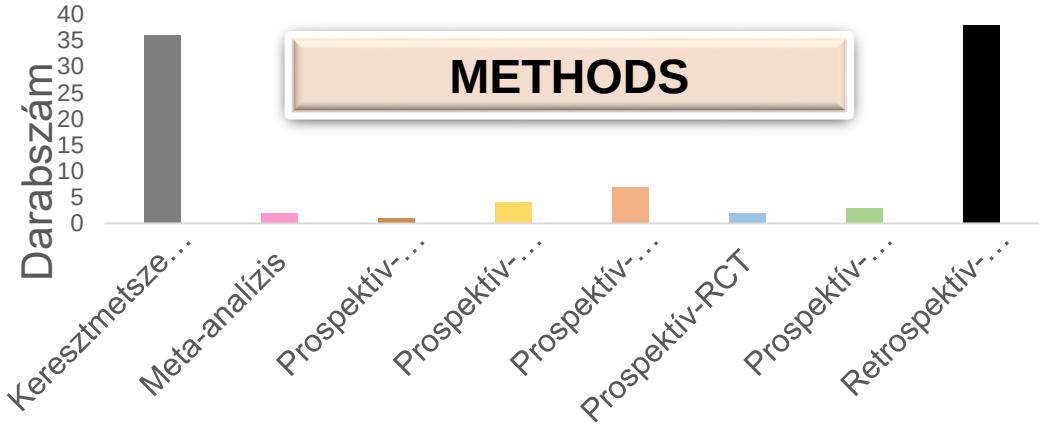
PATIENTS NUMBER



CENTRES



METHODS



TRANSLATIONAL MEDICINE

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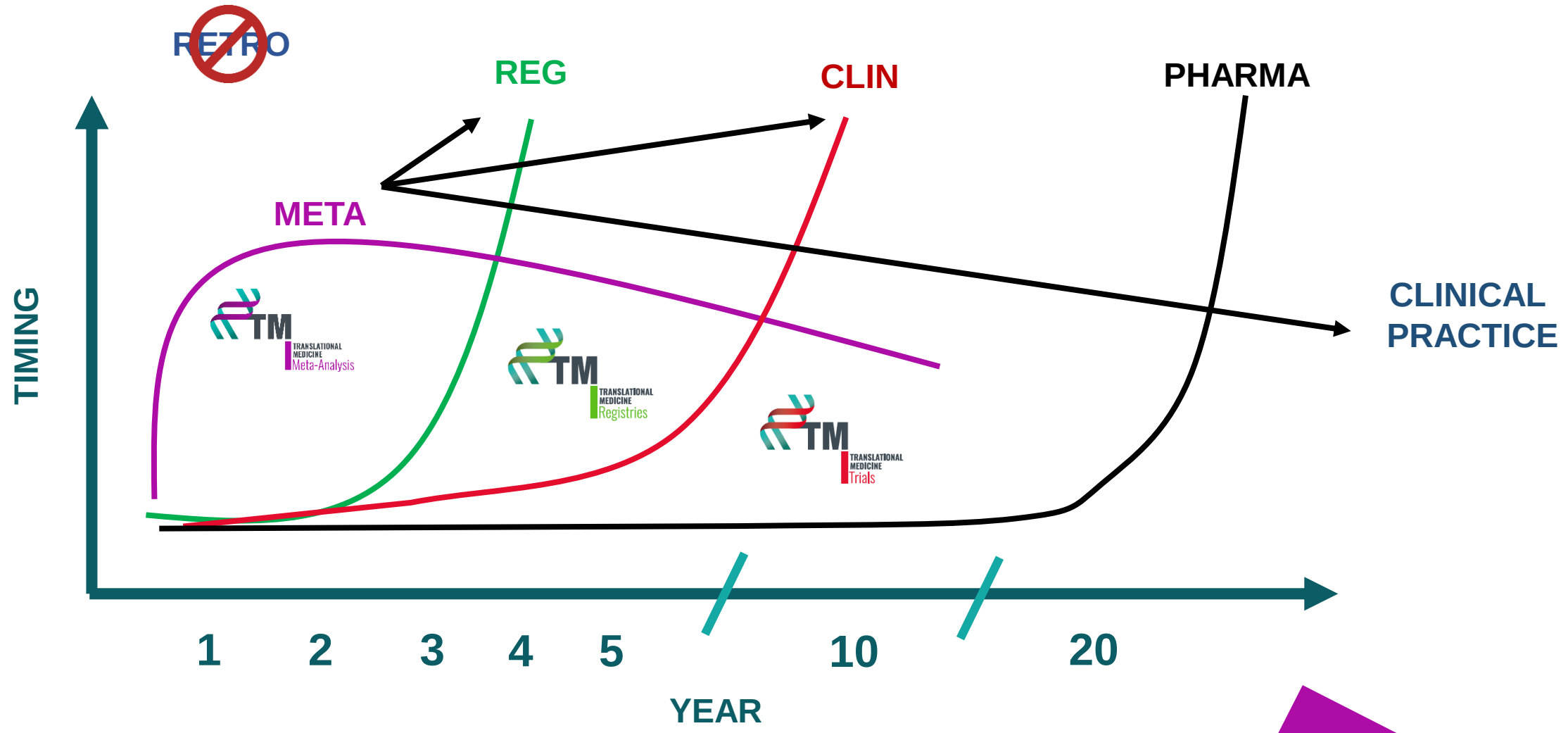

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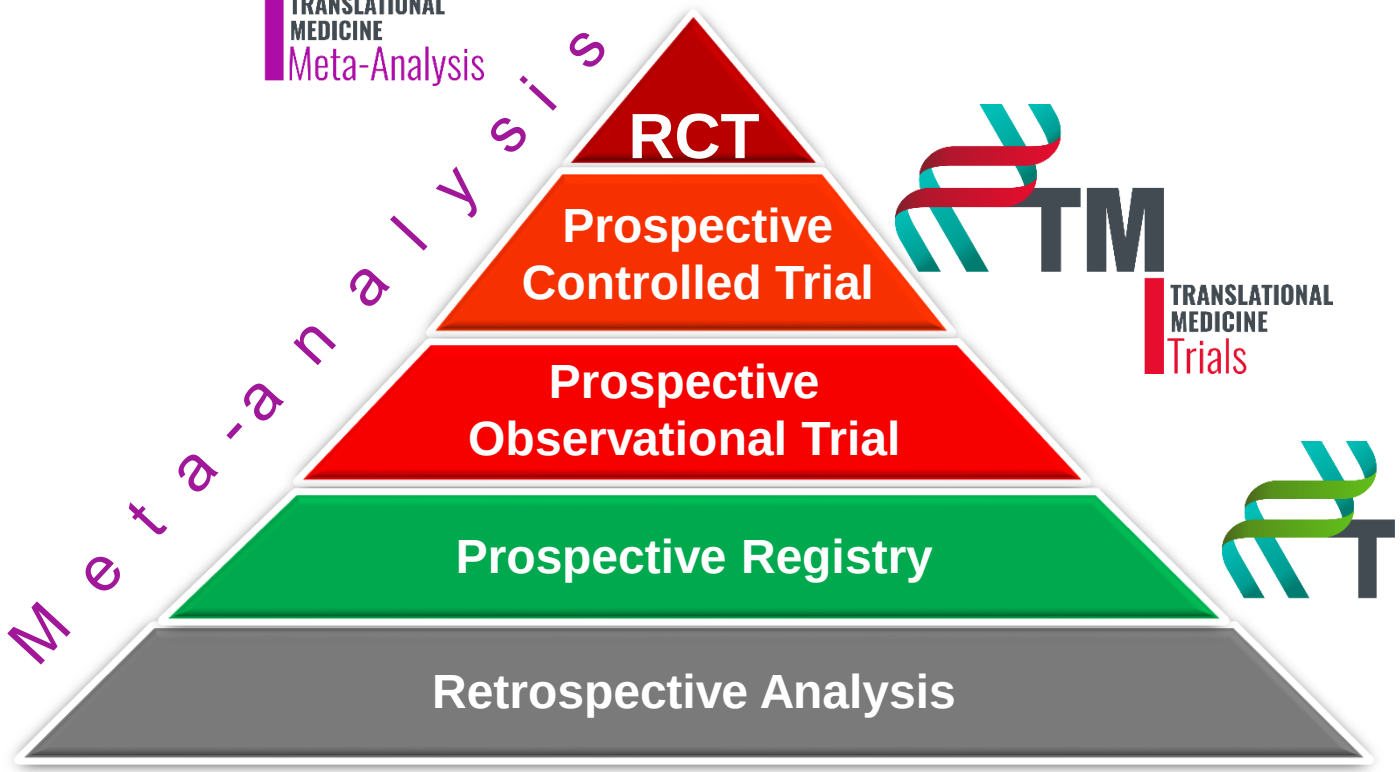
Clinical Research **Methodologies** How can we help?

TM TRANSLATIONAL MEDICINE Meta-Analysis



TM TRANSLATIONAL MEDICINE Trials

TM TRANSLATIONAL MEDICINE Registries

TRANSLATIONAL MEDICINE

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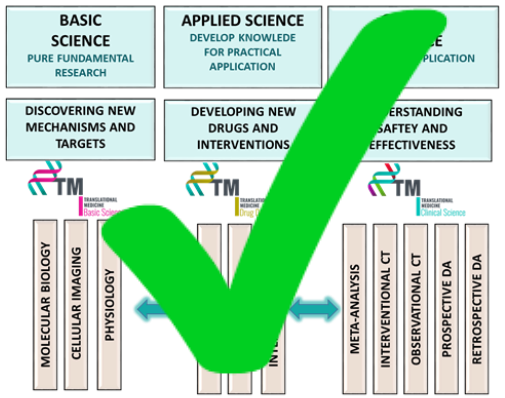
HEALTHCARE

QUESTION

PRACTICE

SCIENCE



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EDUCATION

GRADUATE AND POSTGRADUATE EDUCATION, PATIENT CLUBS DISSEMINATION OF INFORMATION

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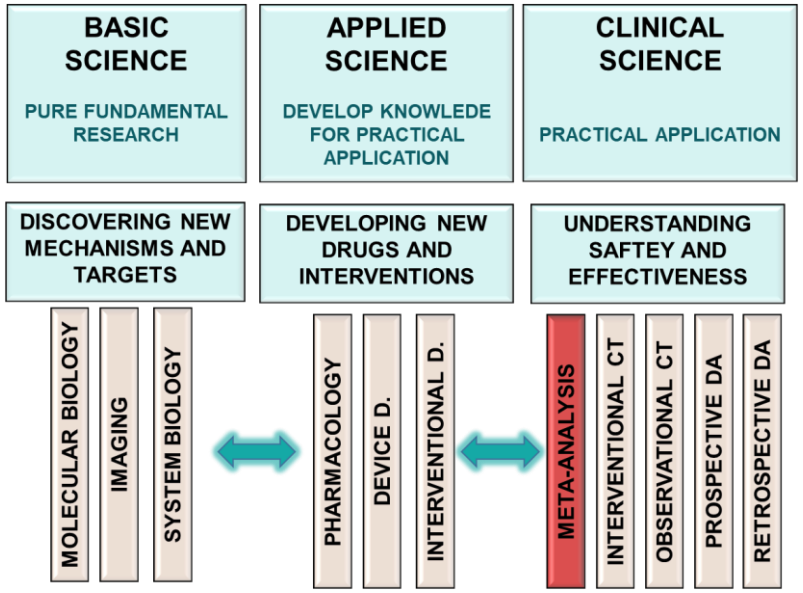
EDUCATION

SCEINTIFIC PUBLICATION

KNOWLEDGE PUBLICATION

KNOWLEDGE

Q5 WHY META-ANALYSIS IS IMPORTANT?



TM TRANSLATIONAL MEDICINE

PubMed

142 000 items

4 months

PubMed

150 000 items

(3rd October, 2018)

Meta-analysis burst

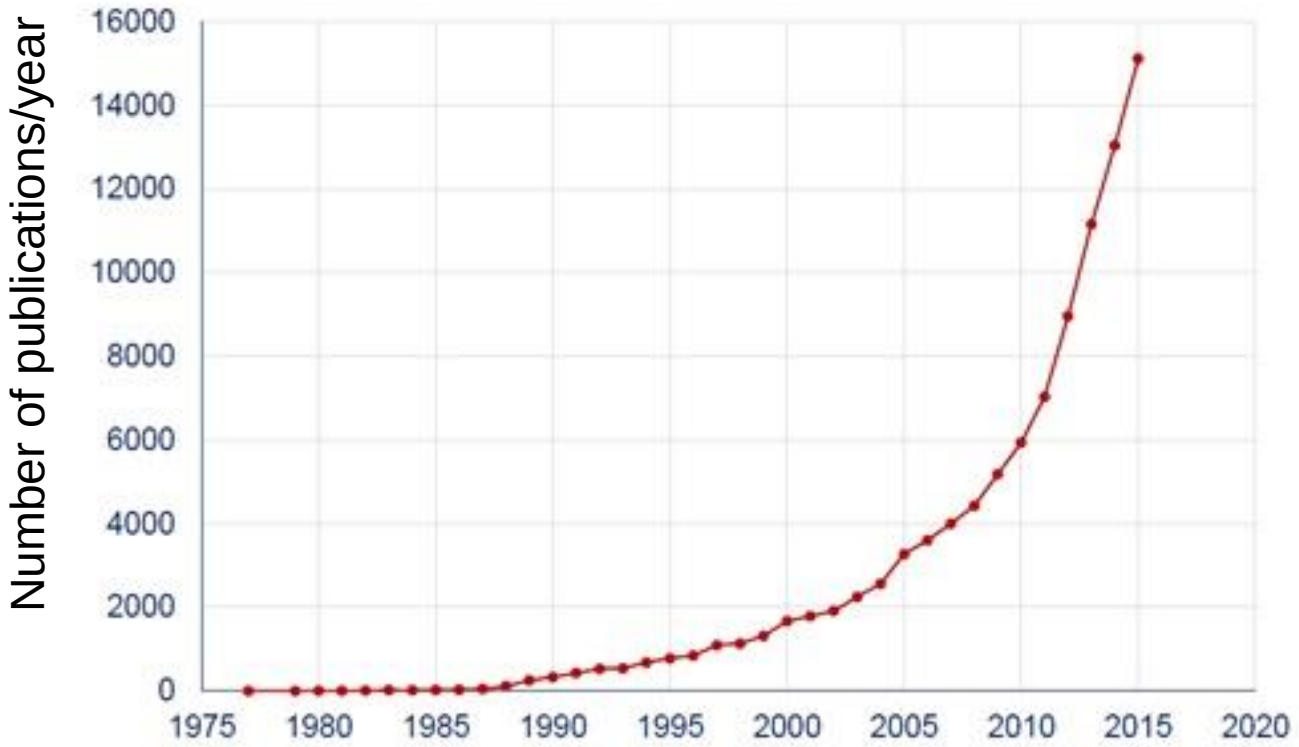


Figure of School of Public Health

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TM TRANSLATIONAL MEDICINE

- NO RESTRICTIONS (BASIC OR CLINICAL)
- EASY TO LEARN
- HELP TO IDENTIFY THE HOLES IN OUR KNOWLEDGE
- EXCELLENT LEARNING METHOD
  OF THE GOOD PUBLICATION PRACTICE
- QUICK ANSWER

TRANSLATIONAL MEDICINE

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- **NO RESTRICTIONS (BASIC OR CLINICAL)**
- **EASY TO LEARN**
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- **EXCELLENT LEARNING METHOD OF THE GOOD PUBLICATION PRACTICE**
- **QUICK ANSWER**

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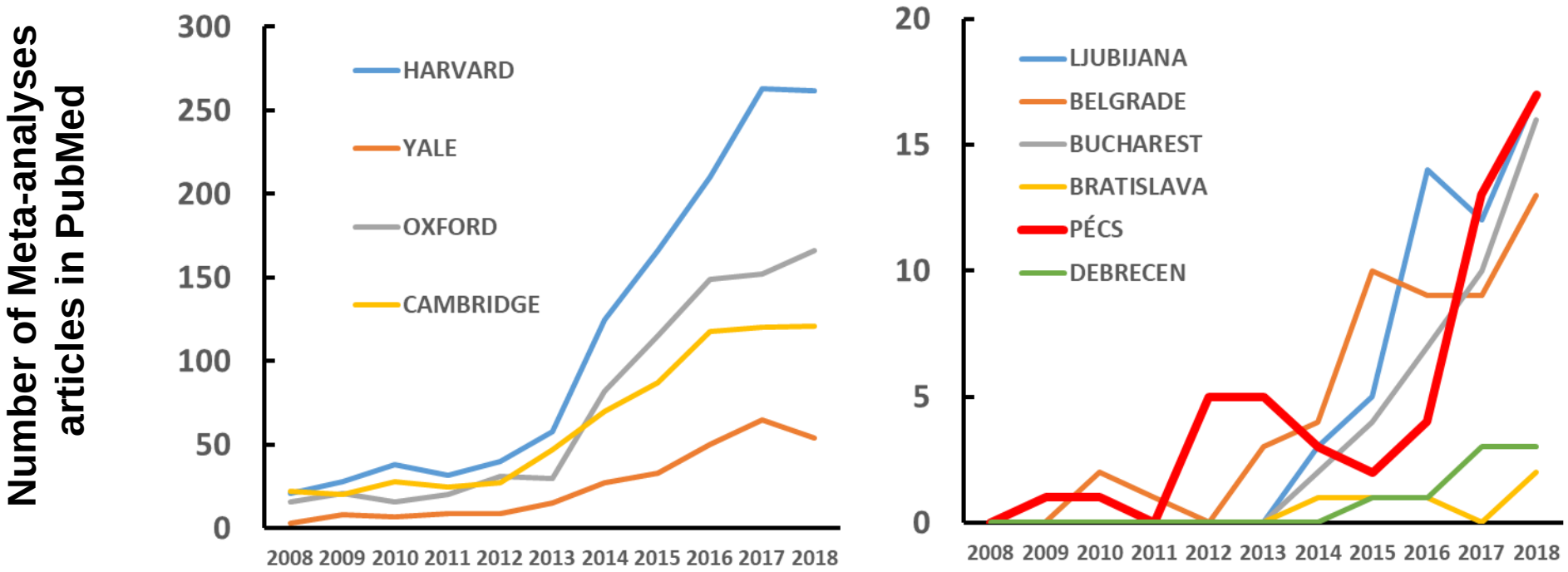
ACTIVITY IN META-ANALYSIS IN THE LAST DECADE



UNIVERSITIES IN EASTERN AND CENTRAL EUROPE ARE FAR AWAY BEHIND THE TOP UNIVERSITIES

TM TRANSLATIONAL MEDICINE

Systematic review

1. Specific question
2. Comprehensive search and selection
3. **Narrative summary** of evidence
4. Answer to the question (if there is any)

Qualitative synthesis

Meta-analysis

1. Specific question
2. Comprehensive search and selection
3. **Statistical summary** of evidence
4. Answer to the question (if there is any)

Quantitative synthesis

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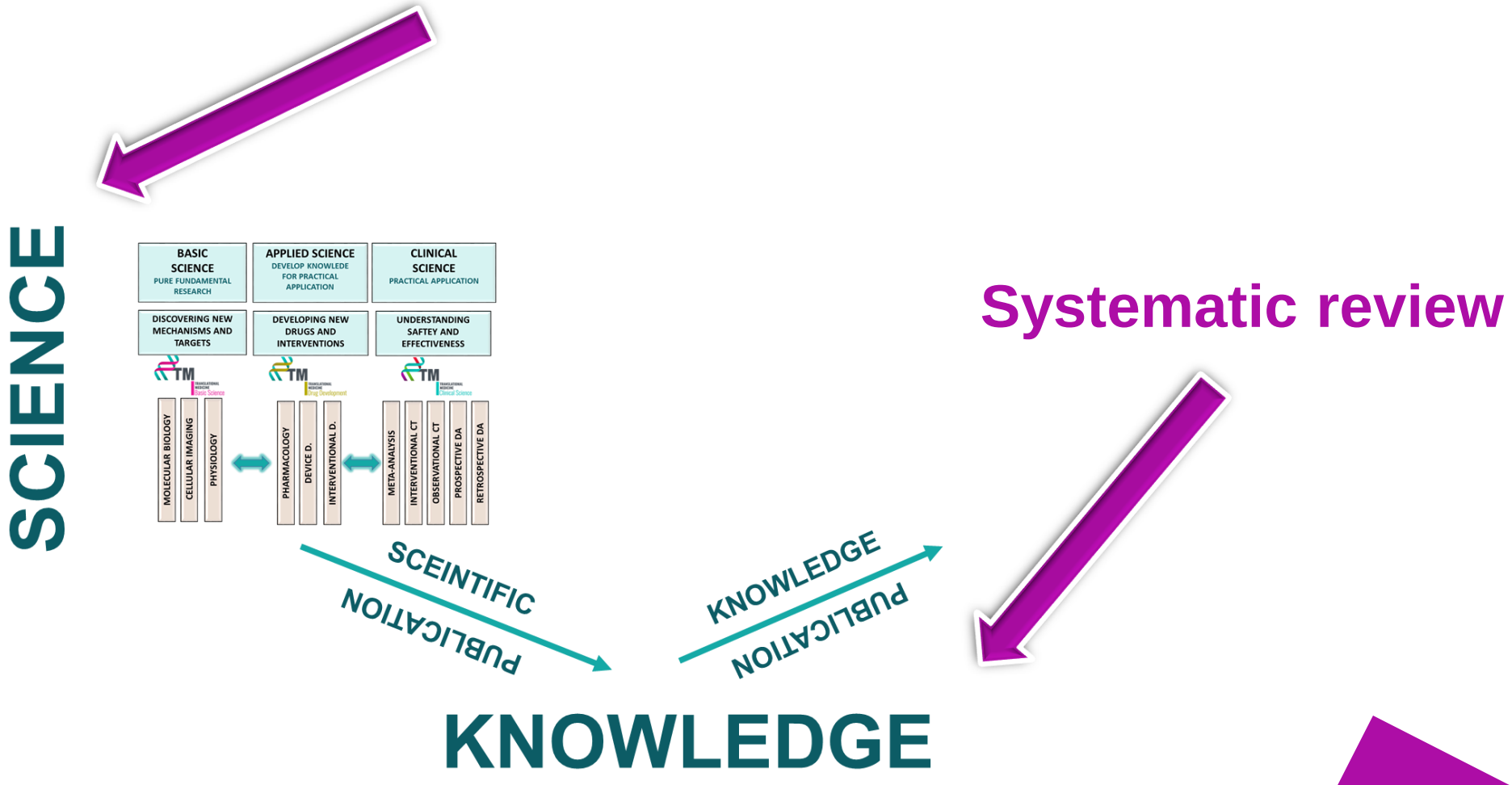
Meta-analysis



Systematic review

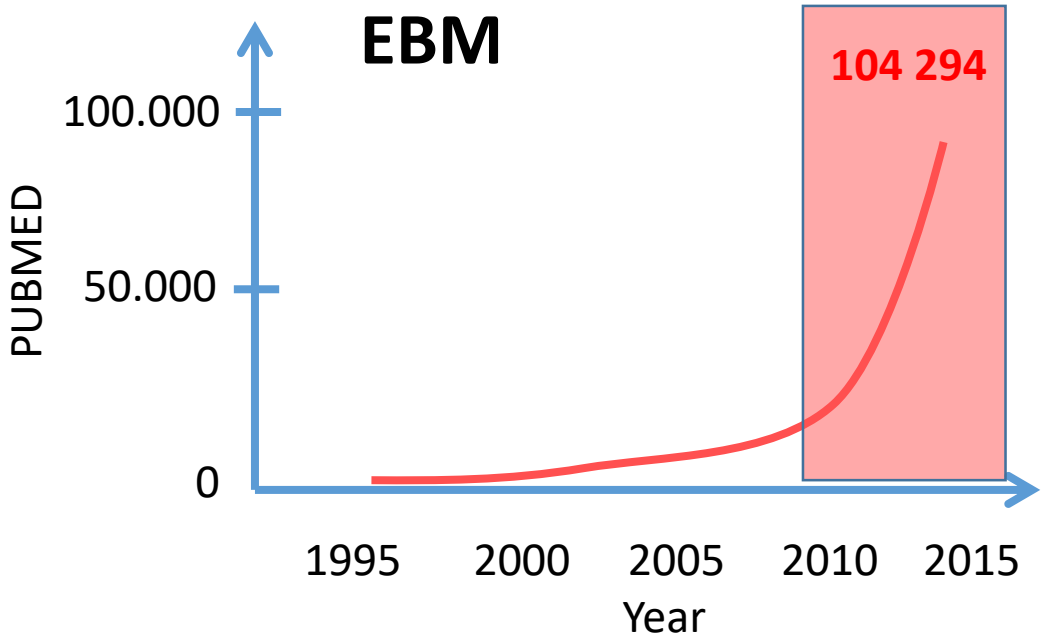
Q6 WHAT IS TRANSLATIONAL KNOWLEDGE?

HISTORICAL OVERVIEW

Published articles only

1967 Feinstein – problems with local, induvidual decision makings

1972 Cochran – randomized clinical trials



Crucially important

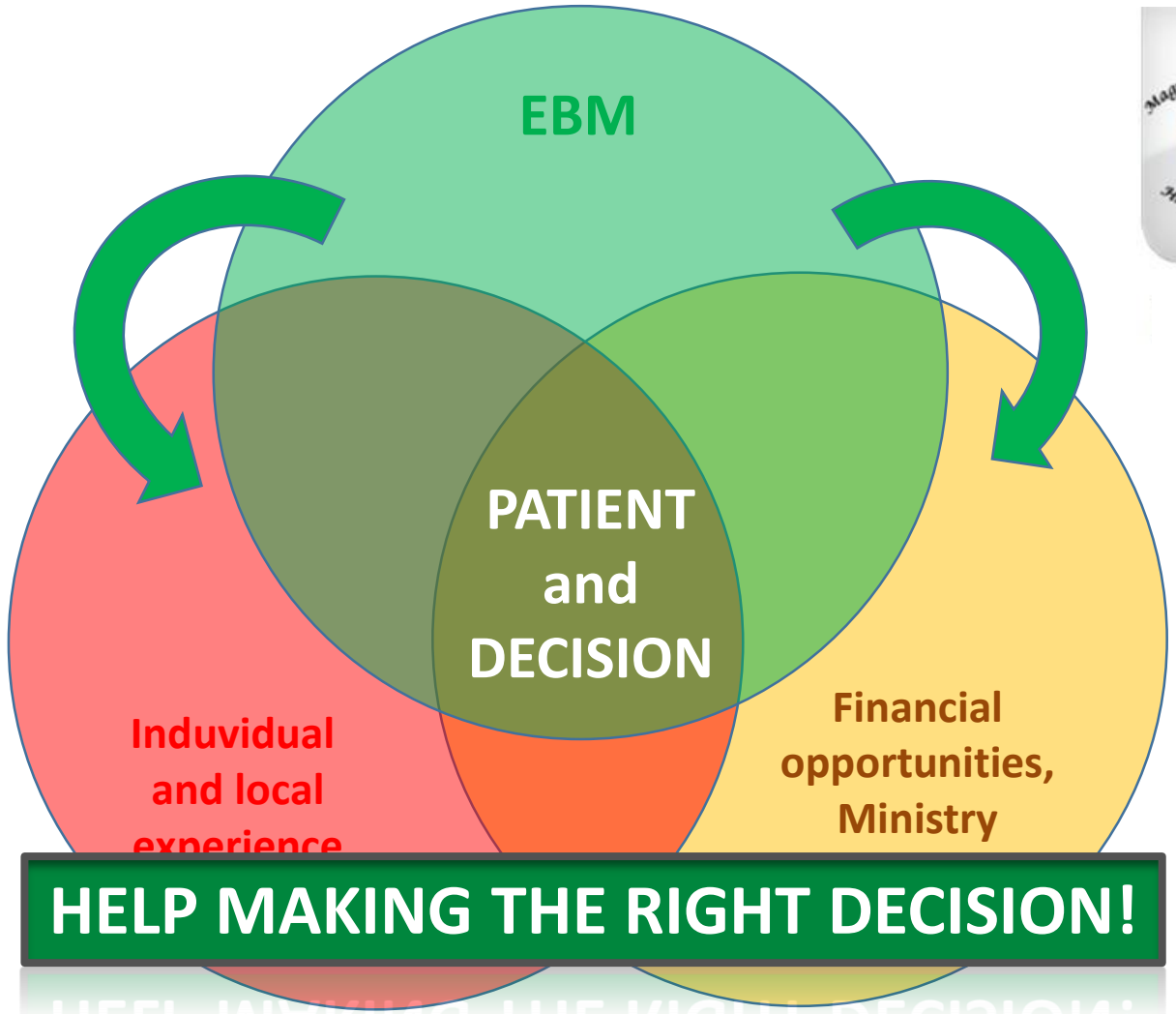
Teaching purposes

Decision makings

Improving financial issues

EBM

Societies' duty



Induvidual and local experience

Financial opportunities, Ministry

HELP MAKING THE RIGHT DECISION!

MIRROR - EBM

09.2012 –04.2014
Acut pancreatitis: 600 patients

	EBM	OTHER
Fluid resuscitation		
Mortality:	1.5%	3.8%
Severe pancreatitis:	11.5%	18.4%
Enteral feeding		
Mortality:	21.79%	47.06%

EBM GUIDELINES ARE ESSENTIAL TO MAKE THE RIGHT DECISION!

MIRROR - EBM

Hungary

Acute pancreatitis

WE COULD SAVE
14k EUROS AND 1 LIVES
EVERY SECOND DAY!

lives:

161 survivors

Hungarian Pancreatic Study Group – Magyar Hasnyálmirigy Munkacsoport

GRADE OF EVIDENCES

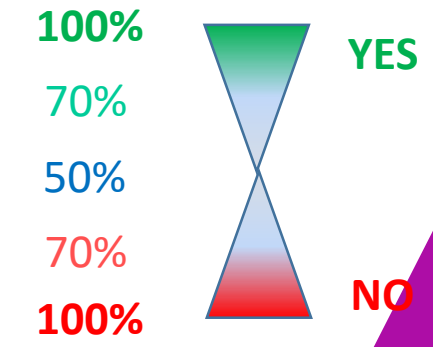
The classification of the evidence was based on the **GRADE Working Group** internationally accepted system, which was established in 2011 (www.gradeworkinggroup.org), and it was applied according to the **UpToDate®** systems guideline (http://www.uptodate. com/home/grading-tutorial#).

GRADE

Strenght of recommendation	Evidence level
1 Strong 2 Weak	A High B Moderate C Low

CONSENSUS

Full agreement
Strong agreement
Weak agreement
Weak disagreement
Strong disagreement



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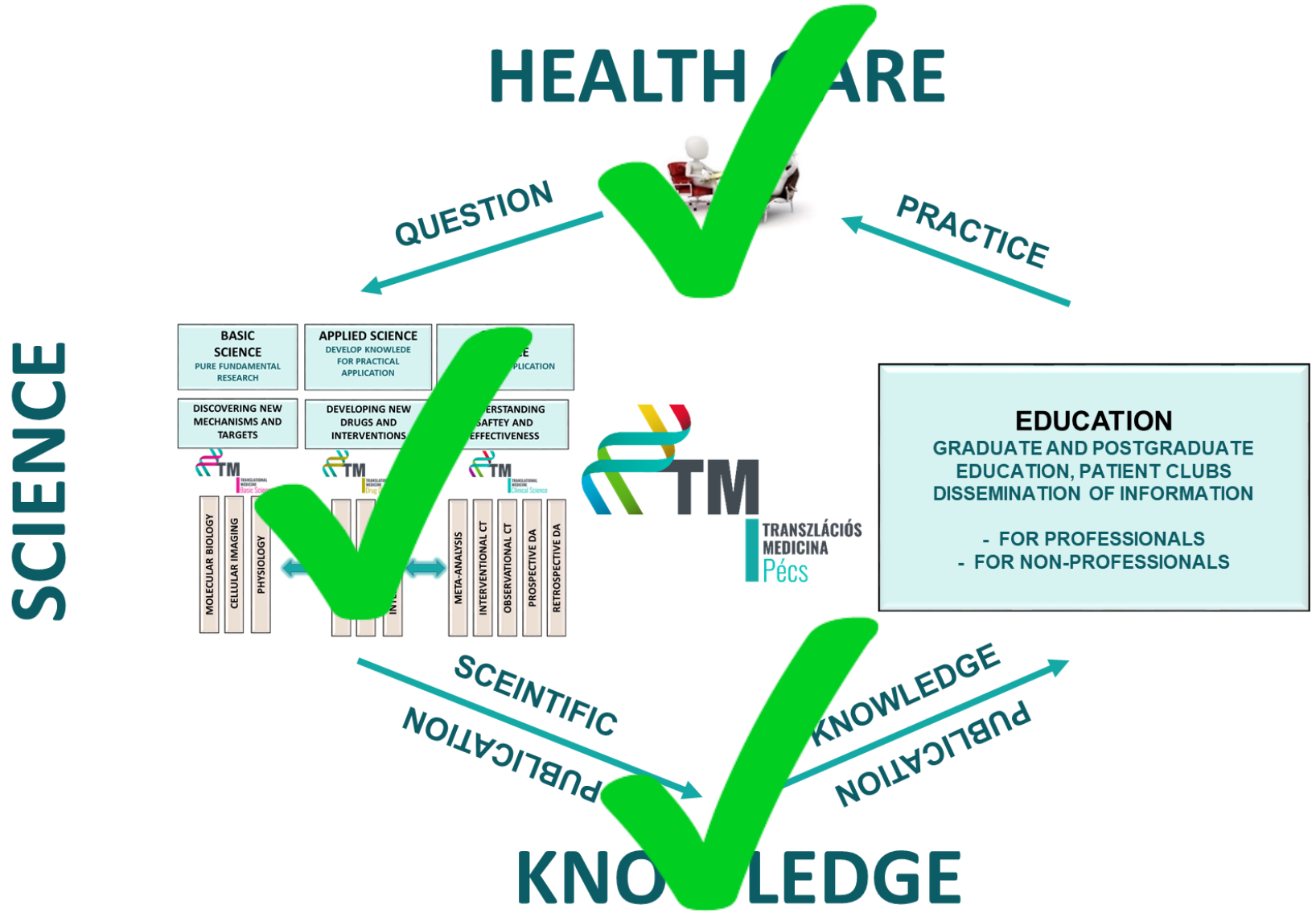

Q7 WHAT IS TRANSLATIONAL EDUCATION?

GRADE OF EVIDENCES

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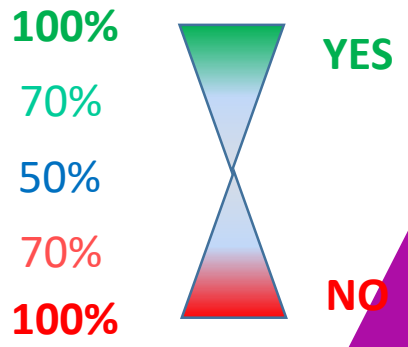
GRADE

Strenght of recommendation		Evidence level	
1	Strong	A	High
2	Weak	B	Moderate
		C	Low

CONSENSUS

Full agreement
Strong agreement
Weak agreement
Weak disagreement
Strong disagreement

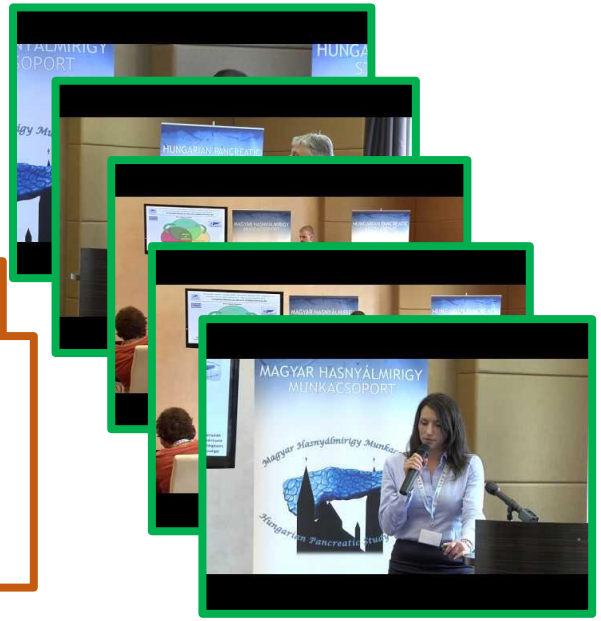


AVAILABLE EBM GUIDELINES

SLIDES

ARTICLES

VIDEO



www.pancreas.hu

Hungarian Pancreatic Study Group – Magyar Hasnyálmirigy Munkacsoport

TRANSLATIONAL MEDICINE

taking discoveries for patients benefits

TRANSLATIONAL MEDICINE

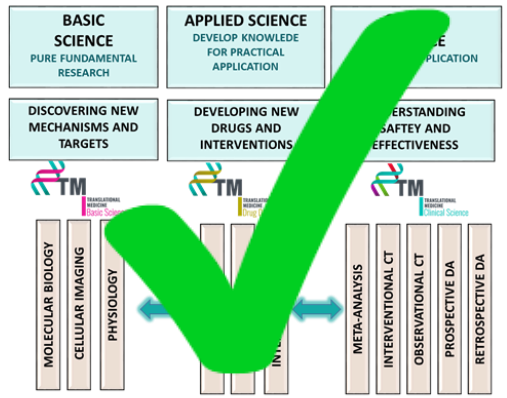
HEALTH CARE

QUESTION

PRACTICE

SCIENCE

EDUCATION



TRANSZLÁCIÓS MEDICINA Pécs

EDUCATI

GRADUATE AND PO ADUATE EDUCATION, PA CLUBS DISSEMINATION ORMATION

- FO ESSIONALS

SCEINTIFIC PUBLICATION

KNOWLEDGE PUBLICATION

KNO LEDGE

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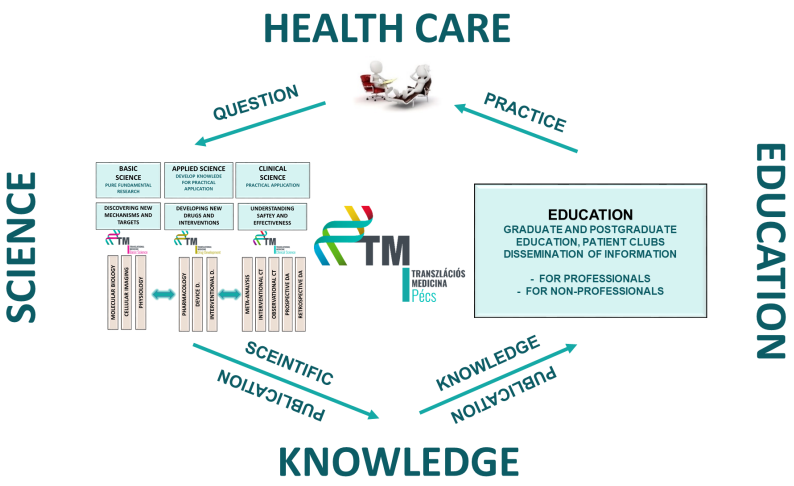
TM TRANSLATIONAL MEDICINE

ESTABLISHMENT

1 JAN 2016

TM University of Pécs Centre for TRANSLATIONAL MEDICINE

NEW APPROACH



INTERDISCIPLINARITY

TM for better healthcare CENTRAL INTERDISCIPLINARY UNIT

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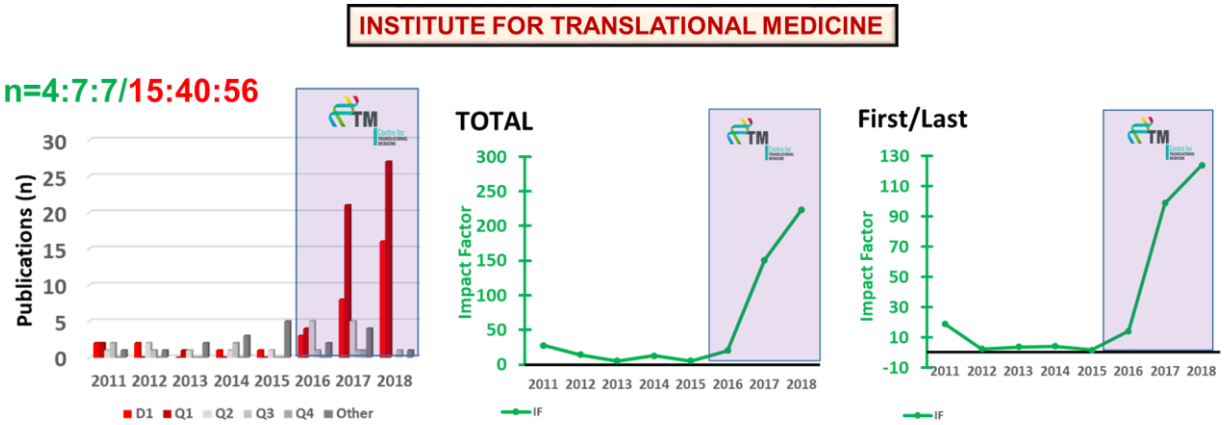
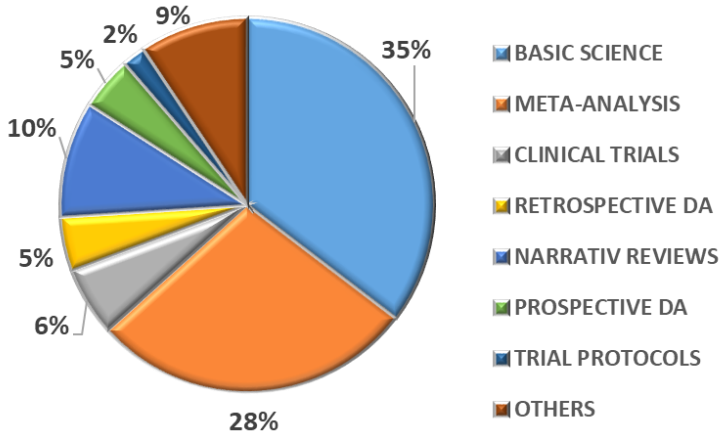
BROAD RANGE OF SCIENTIFIC ACTIVITY



FirstLast/Total	2011	2012	2013	2014	2015	2016	2017	2018
	68%	16%	66%	32%	29%	70%	65,3%	55,5%



150 articles

01.01.2016 – 30.06.2019

10 articles (above IF: 10.0)
21 articles (above IF: 5.0)
Average: 4.188

EXCELLENCE IS A MUST

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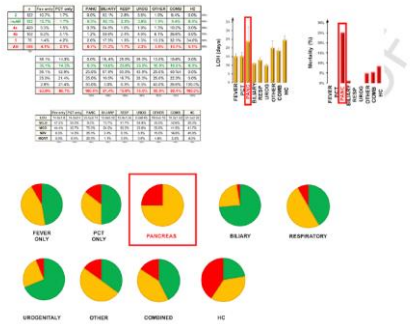
IMMEDIATE PATIENTS' BENEFITS

NECESSITY AND USAGE OF ANTIBIOTICS
DECREASED WITH 50%


Pancreatology

Antibiotic therapy in acute pancreatitis: From global overuse to evidence based recommendations

23 countries
62 centres
9728 patients



Average Daily Costs of AP Therapy

Values in €	AB +	AB -
MILD	76	71
MODERATE	114	106
SEVERE	151	142

Average Costs of AP Therapy per Patient

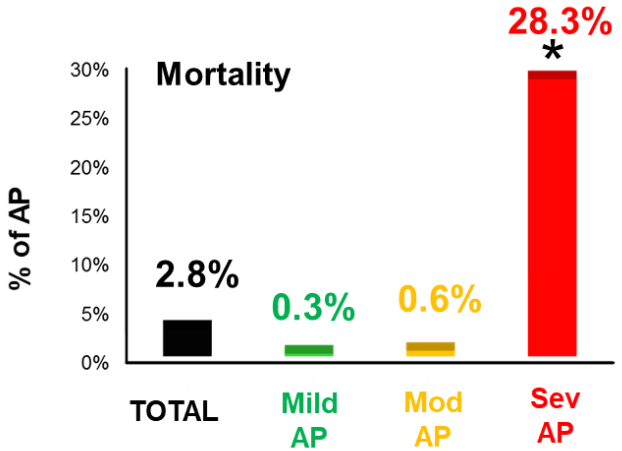
Pancreatic Center 964 € General M. Center 1285

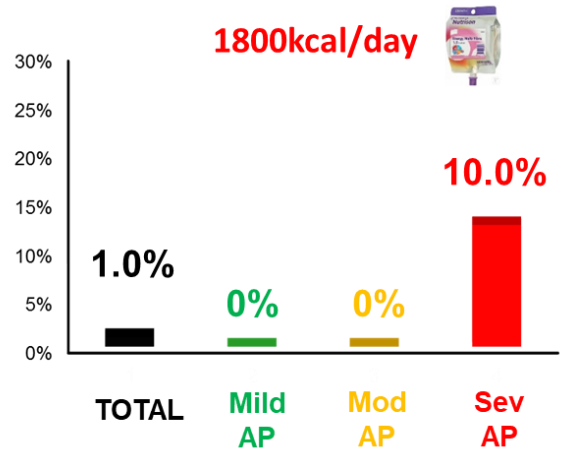
25%

HEALTHCARE COSTS

25%

MORTLITY DECREASED IN ACUTE PANCREATITIS





9 TRIALS ARE RUNNING

TMEASY HUNGARIAN PANCREATIC STUDY GROUP
TMLIFESPAN HUNGARIAN PANCREATIC STUDY GROUP
TMEMILY HUNGARIAN PANCREATIC STUDY GROUP
TMPINEAPPLE HUNGARIAN PANCREATIC STUDY GROUP
TMGOULASH HUNGARIAN PANCREATIC STUDY GROUP
TMPREPAST HUNGARIAN PANCREATIC STUDY GROUP
TMELEFANT HUNGARIAN PANCREATIC STUDY GROUP
TMAPPLE HUNGARIAN PANCREATIC STUDY GROUP
TMANTILOPE HUNGARIAN PANCREATIC STUDY GROUP

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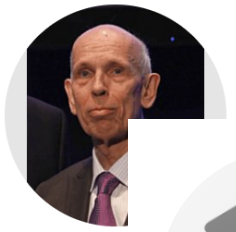


Ole H Petersen

FOLLOW

Professor, Cardiff University

Verified email at cardiff.ac.uk

Cited by		VIEW ALL
	All	Since 2014

TITLE

Calcium-
OH Peters
Nature 307

Synergis
Ca2+-de
AP Morris,
Nature 330

Dennis Brown

FOLLOW

Professor of Medicine, Massachusetts General Hospital

Cited by		VIEW ALL
	All	Since 2014

TITLE

TRPC6 is
normal rer
J Reiser, KR
Nature gene

Localizatic
clusterin ir
genetic re

John Neoptolemos

FOLLOW

Cited by VIEW ALL

TITLE

Postope
definitic
C Bassi,
surgery 1

Postope
definitic
C Bassi,

Stephen Holgate

FOLLOW

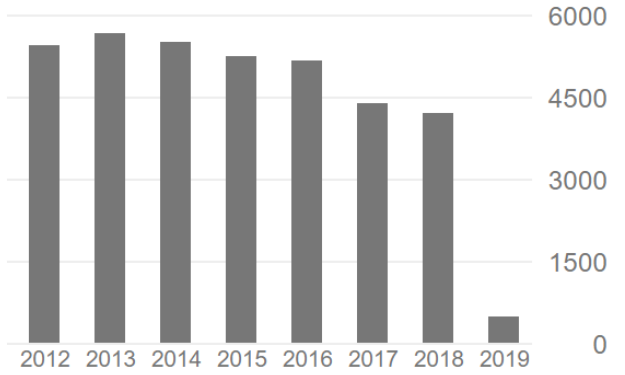
University of Southampton, Faculty of Medicine

Verified email at soton.ac.uk - Homepage

Immunopharmacology allergy asthma pollution

TITLE	CITED BY	YEAR
Air pollution and health B Brunekreef, ST Holgate The lancet 360 (9341), 1233-1242	3372	2002
Community study of role of viral infections in exacerbations of asthma in 9-11 year old children SL Johnston, PK Pattemore, G Sanderson, S Smith, F Lampe, L Josephs, ... Bmj 310 (6989), 1225-1229	1995	1995

Cited by	All	Since 2014
Citations	111319	25151
h-index	163	79
i10-index	939	379



Q9 WHY WE ARE HERE TODAY?

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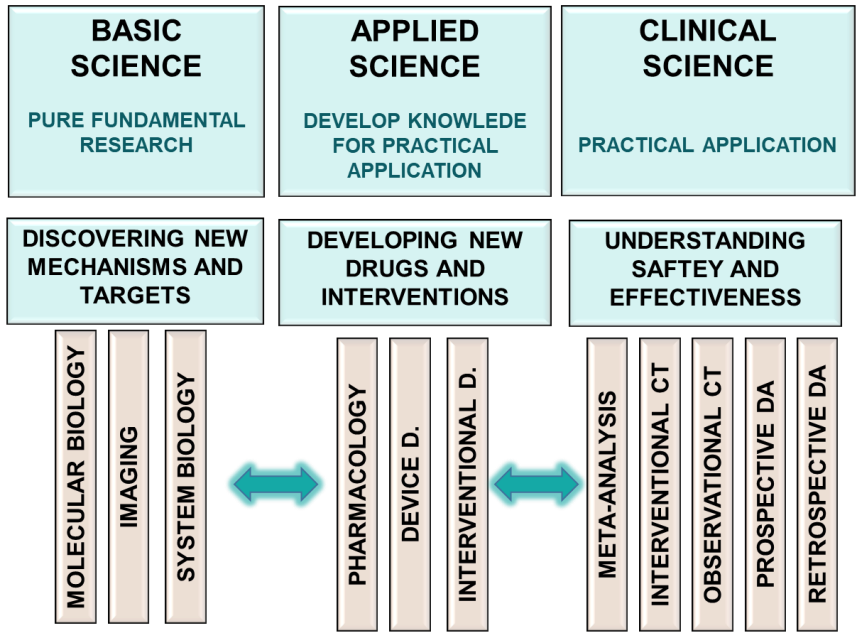
OUR AIM IS TO DEVELOP, APPLY AND SHARE THE KNOWLEDGE OF TM AND OFFER THE SERVICE OF OUR CORE FACILITY



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Thank you for your attention!

Péter Hegyi

p.hegyi@tm-centre.org

www.tm-centre.org

CENTRAL INTERDISCIPLINARY UNIT
for better healthcare

INTERDISCIPLINARY RESEARCH SUPPORT UNIT

Péter Hegyi
Pécs, Hungary

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HEALTH CARE

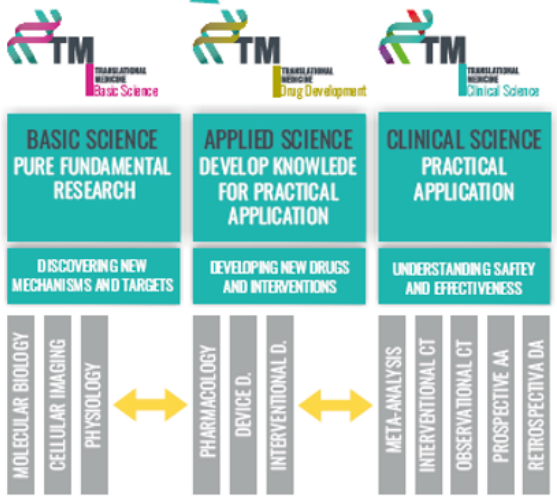
WP1

question

practice

WP2

SCIENCE



TRANSLATIONAL MEDICINE Pécs

PROTOCOL DEVELOPMENT
EVIDENCE BASED MEDICINE (EBM)
EDUCATION
GRADUATE AND POSTGRADUATE EDUCATION, DISSEMINATION OF INFORMATION

WP4

COMMUNICATION

WP5

INTERDISCIPLINARY

WP6

ACADEMY

answer

WP3

KNOWLEDGE

publication

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CENTRAL INTERDISCIPLINARY UNIT

- UNIVERSITY OF PÉCS

CLINICAL RESEARCH SUPPORT

- SZEGED – UNIVERSITY OF SZEGED
- DEBRECEN – UNIVERSITY OF DEBRE

CLINICAL RESEARCH SUPPORT

- SZÉKESFEHÉRVÁR – SZENT GYÖRG
- BUDAPEST - HEIM PÁL NATIONAL IN

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STRATEGY

Péter Hegyi

OPERATION

Andrea Szentesi

MEDICAL GROUP

Bálint Erőss

PHD AND PROF. TRAINING

Zsolt Szakács

METAANALYSIS COORDINATION

Szabolcs Kiss

PATIENT REGISTRY COORDINATION

Vivien Vass

CLINICAL TRIAL COORDINATION

Judit Antal Katalin Márta Noémi Zádori

BIOSTATISTICS GROUP

Nelli Farkas

INFORMATICS GROUP

Richárd Farkas

DATA & PATIENT COORD. GROUP

Emőke Miklós

COMMUNICATION GROUP

Dalma Dobszai

HR & FINANCIAL GROUP

Margit Solymár

HEALTH ECONOMICS GROUP

Antal Zemplényi

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Main tasks

- Translational Medicine program
- Center development
- Organization of translational patient care
- Research support (clinical research)
  - Meta-analyses
  - Patient registries
  - Clinical trials
- Course and textbook development
- Communication

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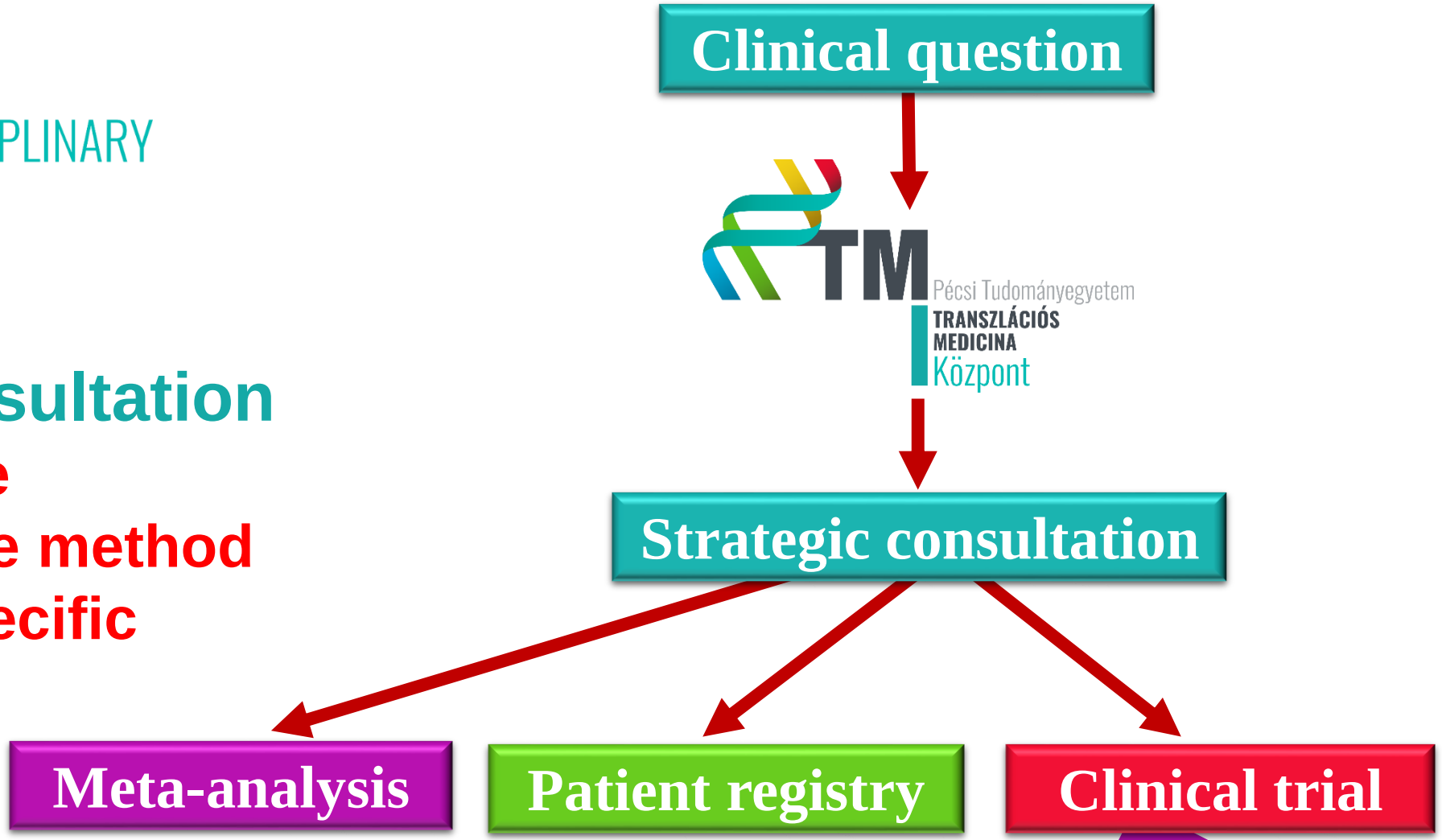
Strategic consultation

- **What is the appropriate method for that specific question?**



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Courses

- methods
  - Meta-analysis course
  - Registry course
  - Clinical trial course

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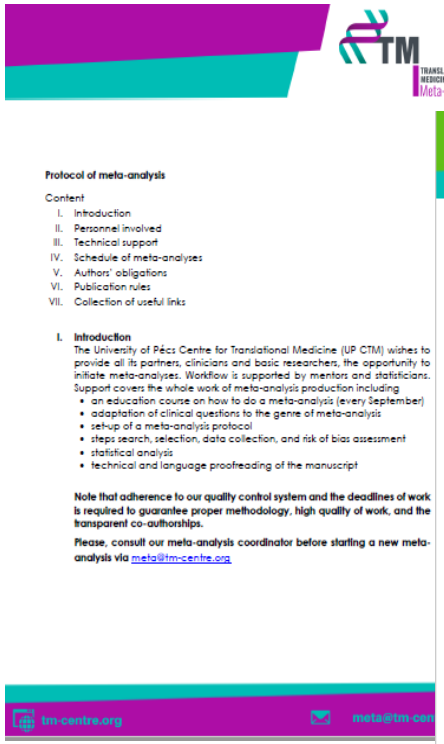
Coordination

- professional coordinators
- Protocols, SOPs



TM Translational Medicine Meta-Analysis

Protocol of meta-analysis

Content

I. Introduction

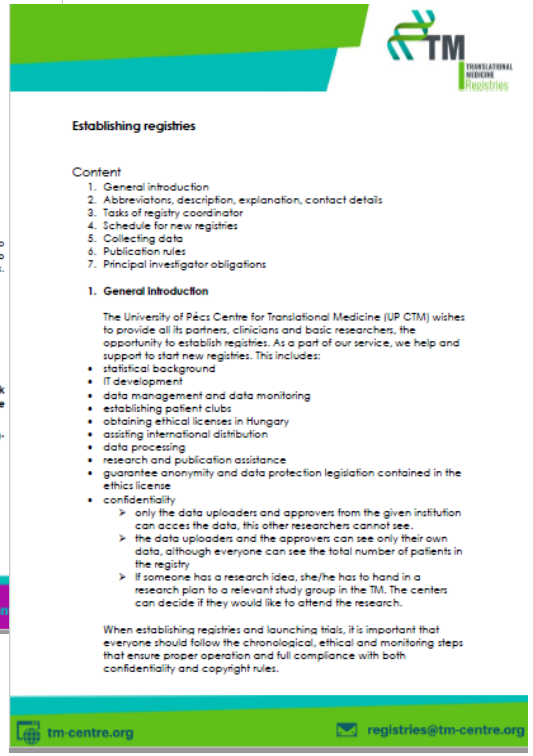
The University of Pécs Centre for Translational Medicine (UP CTM) wishes to provide all its partners, clinicians and basic researchers, the opportunity to initiate meta-analyses. Workflow is supported by mentors and statisticians. Support covers the whole work of meta-analysis production including

- an education course on how to do a meta-analysis (every September)
- adaptation of clinical questions to the genre of meta-analysis
- set-up of a meta-analysis protocol
- steps search, selection, data collection, and risk of bias assessment
- statistical analysis
- technical and language proofreading of the manuscript

Note that adherence to our quality control system and the deadlines of work is required to guarantee proper methodology, high quality of work, and the transparent co-authorships.

Please, consult our meta-analysis coordinator before starting a new meta-analysis via meta@tm-centre.org

tm-centre.org meta@tm-cen



TM Translational Medicine Registries

Establishing registries

Content

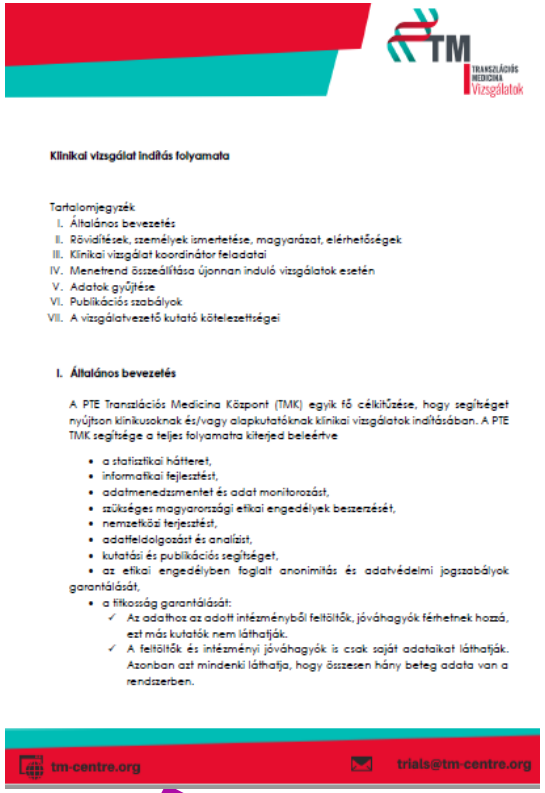
1. General introduction

The University of Pécs Centre for Translational Medicine (UP CTM) wishes to provide all its partners, clinicians and basic researchers, the opportunity to establish registries. As a part of our service, we help and support to start new registries. This includes:

- statistical background
- IT development
- data management and data monitoring
- establishing patient clubs
- obtaining ethical licenses in Hungary
- assisting international distribution
- data processing
- research and publication assistance
- guarantee anonymity and data protection legislation contained in the ethics license
- confidentiality
  - only the data uploaders and approvers from the given institution can acces the data, this other researchers cannot see.
  - the data uploaders and the approvers can see only their own data, although everyone can see the total number of patients in the registry
  - If someone has a research idea, she/he has to hand in a research plan to a relevant study group in the TM. The centers can decide if they would like to attend the research.

When establishing registries and launching trials, it is important that everyone should follow the chronological, ethical and monitoring steps that ensure proper operation and full compliance with both confidentiality and copyright rules.

tm-centre.org registries@tm-centre.org



TM Transzlációs Medicina Vizsgálatok

Klinikai vizsgálat indítás folyamata

Tartalomjegyzék

I. Általános bevezetés

A PTE Transzlációs Medicina Központ (TMK) egyik fő célkitűzése, hogy segítséget nyújtson klinikusoknak és/vagy alapkutatóknak klinikai vizsgálatok indításában. A PTE TMK segítsége a teljes folyamatra kiterjed beleértve

- a statisztikai hátteret,
- informatikai fejlesztést,
- adatmenedzsmentet és adat monitorozást,
- szükséges magyarországi etikai engedélyek beszerzését,
- nemzetközi terjesztést,
- adatfeldolgozást és analízist,
- kutatási és publikációs segítséget,
- az etikai engedélyben foglalt anonimitás és adatvédelmi jogszabályok garantálását,
- a titkosság garantálását:
  - ✓ Az adathoz az adott intézményből feltöltők, jóváhagyók férhetnek hozzá, ezt más kutatók nem láthatják.
  - ✓ A feltöltők és intézményi jóváhagyók is csak saját adataikat láthatják. Azonban azt mindenki láthatja, hogy összesen hány beteg adata van a rendszerben.

tm-centre.org trials@tm-centre.org

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Data & patient coordination


- Informed consent
- patient questionnaires
- biological samples
- data collection, upload, control

IT development

- eCRF
- data bases
- access levels
- networks

HR, financial

- organization
- grants
- events

Statistics

- sample size calculation
- statistical analysis
- statistical methods (publications)

Communnication

- communication (including patient clubs)
- informational materials
- even organization
- website

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	STRATEGIC CONSULTATION AND COORDINATION	ETHICAL PERMISSION	INTERNATIONAL REGISTRATION	INFORMATICS DEVELOPMENT	DATA MANAGEMENT	STATISTICAL SUPPORT
RANDOMIZED CONTROLLED CLINICAL TRIAL	✓	✓	✓	✓	✓	✓
PROSPECTIVE CONTROLLED CLINICAL TRIAL	✓	✓	✓	✓	✓	✓
PROSPECTIVE OBSERVATIONAL CLINICAL TRIAL	✓	✓	✓	✓	✓	✓
PROSPECTIVE PATIENT REGISTRY	✓	✓	✗	✓	✓	✓
META-ANALYSIS	✓	✗	✓	✗	✗	✓

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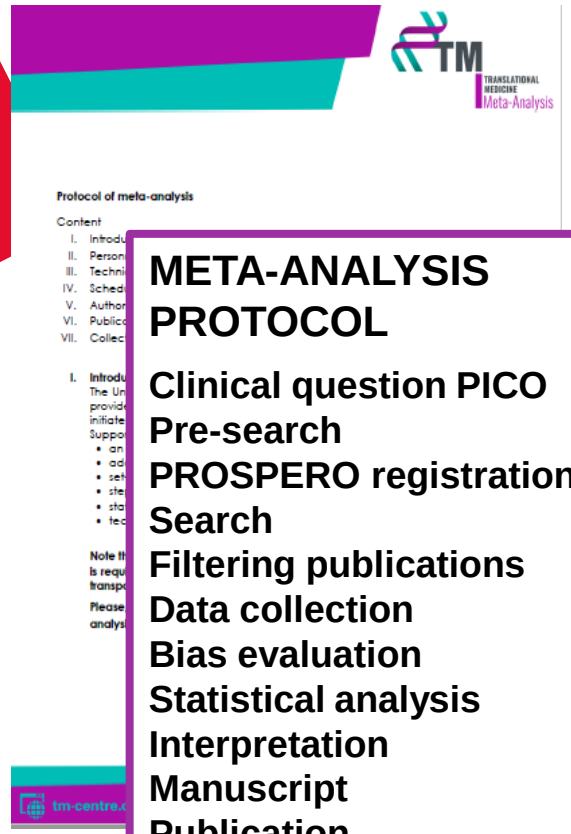
Meta-analyses



META-ANALYSIS PROTOCOL

- Clinical question PICO
- Pre-search
- PROSPERO registration
- Search
- Filtering publications
- Data collection
- Bias evaluation
- Statistical analysis
- Interpretation
- Manuscript
- Publication

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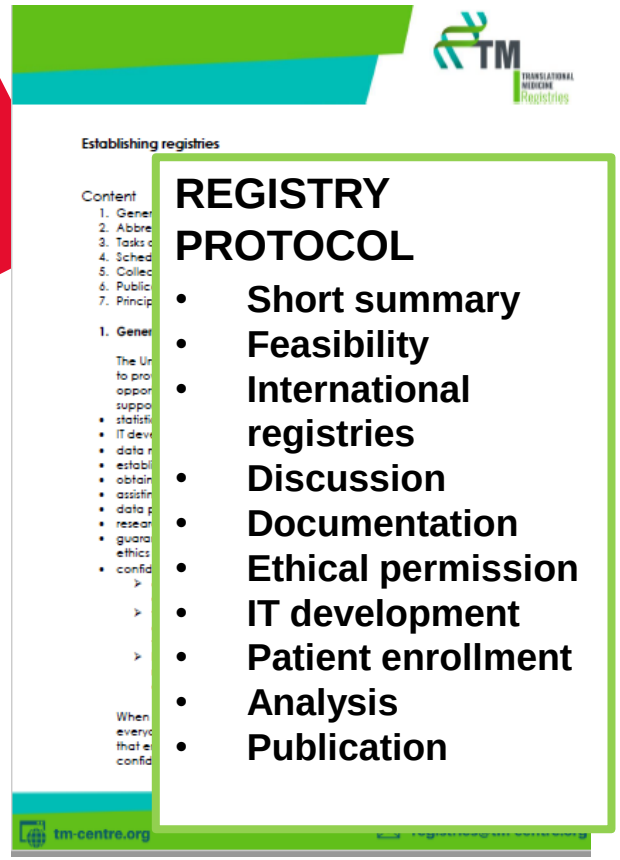
Patient Registries



REGISTRY PROTOCOL

- Short summary
- Feasibility
- International registries
- Discussion
- Documentation
- Ethical permission
- IT development
- Patient enrollment
- Analysis
- Publication

STRATEGY

Péter Hegyi

OPERATION

Andrea Szentesi

MEDICAL GROUP

Bálint Erőss

PHD AND PROF. TRAINING

Zsolt Szakács

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HR & FINANCIAL GROUP

Margit Solymár

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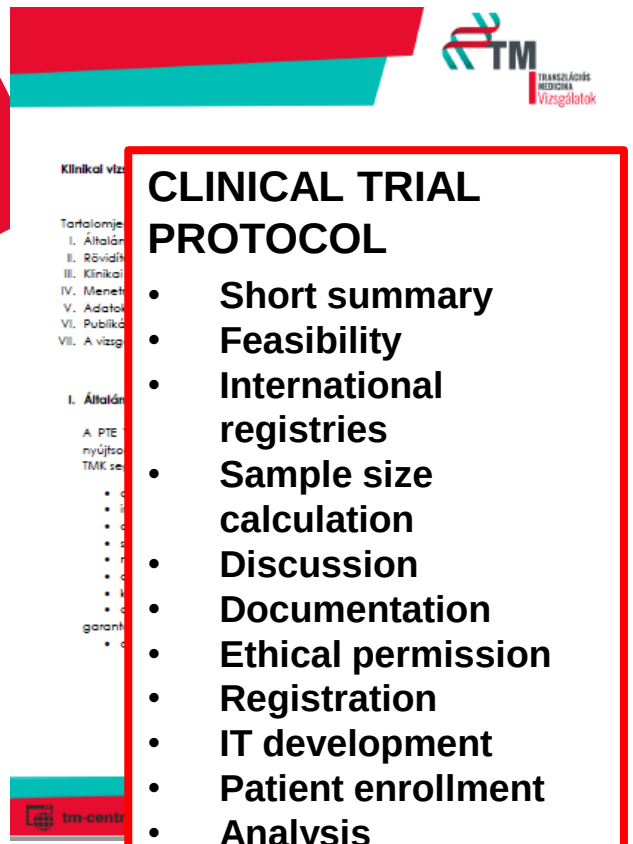
Clinical Trials



CLINICAL TRIAL PROTOCOL

- Short summary
- Feasibility
- International registries
- Sample size calculation
- Discussion
- Documentation
- Ethical permission
- Registration
- IT development
- Patient enrollment
- Analysis
- Publication

2019

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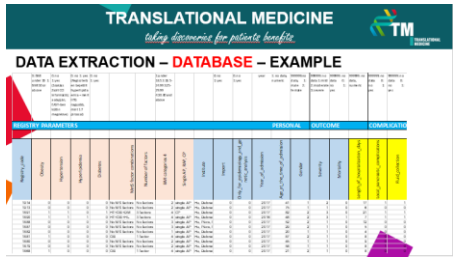
TM TRANSLATIONAL MEDICINE

Ensuring data quality

- Professional coordination
- IT, Data&Patient coord.
- Courses and trainings
- Data upload control system
  - local administrator check (1.)
  - local investigator check (2.)
- In-house monitoring
  - central administrator (3.)
  - central investigator (4.)
- On-site monitoring

Registry course



CRA Training

"A" form

Inpatient day	Form id	State	Approval state	Physician	Form date	Recording date	Bio samples	Actions
1	AP448/A19061205	await inspection	✓✓✓○	Dr. Bajor Judit	6/12/2019 7:50 AM	6/19/2019 10:11 AM		

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Support is free for researchers

- University of Pécs
- GINOP, EFOP grants
- NKFI, ÚNKP
- University grants to cover data administration (University of Pécs)

Responsibilities of the principal investigator

- Continuous professional control
- Follow-up of the projects
- Supervising and controlling inclusions (electronic database)
- Analysis and publication
- Principal investigator can be dismissed if tasks are not fulfilled (for the interest of the other participants of the projects)

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for better healthcare

Clinical Trials	**16 (9)**
Patient Registries	**34 (20)**
Meta-analyses	**101 (41)**

„TAKE HOME" MESSAGE

1) The **interdisciplinary unit** supports the planning, development and running of research projects (meta-analyses, patient registries and clinical trials).
2) Main areas: **strategic consultation**, **professional coordination**, **biostatistics**, **informatics**, **data management**, **health economics**.
3) **Professional control** from the principal investigator is crucial!
4) **We are happy to support your research projects!**

Thank you for your attention!

Registry coordinator

Vass Vivien

e-mail: registries@tm-centre.org

phone:

+36 30 571 8188

+36 72 536 000 / 31885

TRANSLATIONAL MEDICINE Registries

www.tm-centre.org

The decision about the registry, aims and international research

Andrea Párniczky
Pécs, Hungary

Definition

A patient registry is an **organized system** that uses observational study methods to **collect uniform data** (clinical and other) to evaluate specified **outcomes** for a population defined by a particular disease, condition, or exposure, and that serves a **predetermined scientific, clinical, or policy purpose(s).**

Gliklich RE, Dreyer NA: Registries for Evaluating Patient Registries: A User's Guide: AHRQ publication No. 07-EHC001. Rockville, MD. April 2007

A patient registry can be a powerful tool

-to observe the **course of disease**;
-to understand **variations** in treatment and outcomes;
-to examine factors that **influence prognosis and quality of life**;
-to describe care patterns, including **appropriateness of care** and disparities in the delivery of care;
-to assess **effectiveness**;
-to monitor **safety and harm**;
-to measure **quality of care;**

Advantages

- observe **every-day clinical practice**
- collect all of the information needed to **assess patient outcomes** in a generalizable way
- outcomes reported are **more representative** („real-world practice")
- evaluate patient outcomes when clinical trials
    - are not practical (e.g., very rare diseases)
    - are not ethically acceptable
    -difficult to conduct (surgery, very long-term outcomes)
- data can be used for **sample size calculation or optimizing protocol** for further clinical trial

BUT:

- interpreting this information correctly requires **analytic methodology** geared to address the potential sources of bias
- requires checks of **internal validity**
- **external data sources** to validate key assumptions
- design is **not suitable to test hypothesis**
- **„Association„** can be drawn

How can we start?

- What is/are your/our aim(s)?
- Is registry the best way to acheive it/them?
- International registry? Other national registry?
- EBM guidelines, position papers
- Cohort analysis
- Acute/chronic registry

Management of Familial Adenomatous Polyposis in Children and Adolescents: Position Paper From the ESPGHAN Polyposis Working Group

*Warren Hyer, †Shlomi Cohen, ‡Thomas Attard, §Victor Vila-Miravet, ||Corina Pienar, ¶Marcus Auth, #Seth Septer, *Jackie Hawkins, **Carol Durno, and *Andrew Latchford

Should children and families with familial adenomatous polyposis be managed within a polyposis registry?

Recommendation 9:
Where feasible, children and adolescents should be enrolled into their regional or national polyposis registry (depending on local and national provision) to coordinate their care. Polyposis registries improve outcome for FAP patients by improving the rate of diagnosis of FAP and reduce the incidence of CRC.
(weak recommendation, moderate-quality evidence, consensus agreement 100%)

Management of Juvenile Polyposis Syndrome in Children and Adolescents: A Position Paper From the ESPGHAN Polyposis Working Group

*Shlomi Cohen, †Warren Hyer, ‡§Emmanuel Mas, ||Marcus Auth, ¶Thomas M. Attard, #Johannes Spalinger, †Andrew Latchford, and **Carol Durno

TABLE 7. Areas requiring research in the field of juvenile polyposis

Does a specific paediatric colonic juvenile polyposis phenotype predict colorectal cancer risk in adulthood?
Are children and adolescents with 4 or 5 metachronous juvenile polyps and no identifiable mutation at risk of gastrointestinal malignancies in adulthood?
Chemoprevention in juvenile polyposis including collaboration with basic scientists to better understand underlying mechanisms.
Well characterized juvenile polyposis kindreds with multiple affected members and no identifiable mutation require genomic evaluation in order to identify additional genes involved in juvenile polyposis phenotypes.

How can we start?

- What is/are your/our aim(s)?
- Is registry the best way to acheive it/them?
- International registry? Other national registry?
- EBM guidelines, position papers
- Cohort analysis
- Acute/chronic registry

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ACUTE PANCREATITIS | **FORM B Further days** | **Patient Questionnaire**

PANCREAS REGISTRIES — PANCREATIC STUDY GROUP

1. Patient personal details

RegisterAP No:

Doctor code:

Name: .....

Pediatric pancreatitis: yes / no / no data

Admission date: .....

Last day of treatment: .....

2. Status

Blood pressure (Hgmm):.....

Body weight (kg):.....

Respiratory rate (/minute):.....

Oxygen saturation (%): .....

Abdominal tenderness: yes / no / no data

Jaundice: yes / no / no data

Heart rate (/minute):.....

Body height (cm):.....

Body temperature (axillary, °C): .....

Previous O2 therapy: yes / no / no data

Abdominal guarding: yes / no / no data

3. Lab results (if any)

Amylase increased more than 3x yes / no / no data

Lipase increased more that 3x yes / no / no data

Amylase (U/l)	
Lipase (U/l)	
White blood cell (WBC) count (G/l)	
Red blood cell (RBC) count (T/l)	
Hemoglobin (g/l) Conversion: mmol/l	
Hematocrit (%)	
Thrombocyte (G/l)	
Glucose (mmol/l) Conversion: mg/dL	
Blood urea nitrogen (mmol/l) Conversion: mg/dL	
Creatinine (umol/l) Conversion: mg/dL	
eGFR	
C-reactive protein (mg/l)	
ASAT/GOT (U/l)	
Lactate dehydrogenase LDH (U/l)	
Calcium (mmol/l)	

Only arterial blood gas parameters should be registered. Please indicate the measuring condition of blood gas parameters

Measuring conditional of blood gas parameters: N/A / room air / 100% O_2

Previous O2 therapy: yes / no / no data

Sodium (mmol/l)	
Potassium (mmol/l)	

tm-centre.org

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FORM A Admission form | **FORM B Follow-up** | **FORM C Complication form** | **FORM E Endoscopic form** | **FORM P Pregnancy form**

CROHN'S DISEASE

IBD REGISTRY — CROHN'S AND COLITIS STUDY GROUP

Patient personal details

Country:

City:

Hospital:

Doctor:

Insurance number:.....

Name:.....

Date of birth:.....

Contact number:.....

Pregnancy

Was the patient pregnant before? yes/ no

If yes, the number of conceivings:.....(piece)

the number of live births:.....(piece)

Pregnancy: yes/ no

if yes, the date of pregnancy:.....(year, month)

the way of getting pregnant: spontaneous / assisted reproduction

number of pregnancy weeks:..... (weeks)

Disease activity:

At conception: active/ in remission	CDAI:.....points
First trimester: active/ in remission	CDAI:..... points
Second trimester: active/ in remission	CDAI:..... points
Third trimester: active/ in remission	CDAI:..... points

Live birth: yes/ no

Premature birth: yes/ no

Caesarean operation: yes/ no

The weight of the newborn baby:.....(gramm)

APGAR of the newborn baby (0. minute): ...../10

APGAR of the newborn baby (10. minute): ...../10

Congenital Developmental Disorder: yes/ no

If yes, type of the Congenital Developmental Disorder:.....

Abortion: yes/ no

If yes: artificial/ spontaneous

Ectopic pregnancy: yes/ no

Shared data structure

Alcohol consumption: yes / no / no data

if yes: frequency: occasionally/monthly/weekly/daily
amount (g/occassion):.....
For how many years? .....
Total alcohol consumption in the last 2 weeks: .....

if not: Did the patient drink alcohol earlier? yes/no/ no data
if yes: frequency: occasionally/monthly/weekly/daily
amount (g/occasion):.....
For how many years?.....
How long ago did the patient stop drinking alcohol?.....

Guide for estimation of the amount:
1 dl beer (4.5 vol. %) = ~3.5 g alcohol
1 dl wine (12.5 vol. %) = ~10 g alcohol
1 dl hard drink (50 vol. %) = ~40 g alcohol

Smoking: yes / no/ no data

if yes: amount (cigarettes/day):.....
How many years ago have you started? .....
Pack year (automatically calculated) .....

if not: Did the patient smoke earlier? yes/no/ no data
if yes: amount (cigarettes/day):.....
For how many years?.....
Pack year: (automatically calculated) .....
How long ago did the patient stop smoking? .....

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Biobank

Am J Gastroenterol. 2017 Dec;112(12):1896-1898. doi: 10.1038/ajg.2017.393.

Novel PRSS1 Mutation p.P17T Validates Pathogenic Relevance of CTRC-Mediated Processing of the Trypsinogen Activation Peptide in Chronic Pancreatitis.

Németh BC[1,2], Szücs Á[3], Hegyi P[4,5], Sahin-Tóth M[1].

page: www.elsevier.com/locate/pan

Pancreas. 2019 Feb;48(2):e12-e14. doi: 10.1097/MPA.0000000000001214.

Evaluation of the Pathogenic Significance of the Novel p.T58M Chymotrypsin C Variant in Recurrent Acute Pancreatitis.

Németh BC[1], Hegyi P, Takács T.

ate secreting anion exchanger

Eszter Hegyi, MD,† Andrea Geisz, PhD,*‡ Miklós Sahin-Tóth, MD, PhD,‡ Monique H. M. Derikx, MD,‡ Balázs Csaba Németh, MD, PhD,‡ Anita Balázs, MD,* István Hritz, MD, PhD,* Ferenc Izbéki, MD, PhD,§ Adrienn Halász, MD,§ Andrea Párniczky, MD,|| Tamás Takács, MD, PhD, DSc,**

egyi [a,c], István Hritz [a], László Czakó [a], aba Németh [d], Judit Gervain [e], Ferenc Izbéki [e], Adrienn Halász [e], Dezső Kelemen [f], Richárd Szmola [g], János Novák [h], Stefan Crai [h], Anita Illés [i], Áron Vincze [i], Zsolt Molnár [j], Márta Varga [k], Barnabás Bod [l], Gyula Farkas Jr. [m], János Sümegi [n], Attila Szepes [o], Zsolt Dubravcsik [o], Natália Lásztity [p], Andrea Párniczky [p], es [r], Zsolt Szentkereszty [s], s Sahin-Tóth [d,1], Jonas Rosendahl [b,1], n Pancreatic Study Group

PLoS One. 2018 Nov 8;13(11):e0206869. doi: 10.1371/journal.pone.0206869. eCollection 2018.

The common truncation variant in pancreatic lipase related protein 2 (PNLIPRP2) is expressed poorly and does not alter risk for chronic pancreatitis.

Németh BC[1,2], Pesei ZG[1,2], Hegyi E[1,3], Szücs Á[4], Szentesi A[2,3], Hegyi P[3,5], Lowe ME[6], Sahin-Tóth M[1].

MDPI

A Common CCK-B Receptor Intronic Variant in Pancreatic Adenocarcinoma in a Hungarian Cohort

Anita Balázs, MD,
First Department of Medicine, University of Szeged, Szeged, Hungary

Article

Genetic Analysis of Human Chymotrypsin-Like Elastases 3A and 3B (CELA3A and CELA3B) to Assess the Role of Complex Formation between Proelastases and Procarboxypeptidases in Chronic Pancreatitis

Andrea Párniczky [1,†], Eszter Hegyi [1,†], Anna Zsófia Tóth [1], Ákos Szücs [2], Andrea Szentesi [3,4], Áron Vincze [5], Ferenc Izbéki [6], Balázs Csaba Németh [4], Péter Hegyi [3,4] and Miklós Sahin-Tóth [1,*]

'TAKE HOME MESSAGE'

1. Be sure that **establishing a registry is the best way** to answer your questions and reach your scientific aims
2. Incorporate the knowledge and experience of **international registries**
3. Use the **shared data structure** to elevate the impack of your work
4. Collect biomedical sample to build up a **disease specific biobank**

Thank you for your attention!

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PRACTICE:

Registry Article Overview

Zsolt Szakács
Pécs, Hungary

6 Question

6 Answers

Each group presents 1 Answer

1. What is the objective/hypothesis of the study?

2. Why is the question raised important (so what???)?

3. What are the major data sources? Can you judge how reliable they are?

4. What are the eligibility criteria? Would you add extra criteria or subtract any of them?

5. Why did use standardized incidence instead of raw incidence?

6. How long is the observation period? Does it impose any form of bias?

Thank you for your participation!