

# Update in ***Autoimmunità e Allergologia***

• **24-25 FEBBRAIO 2023**

**Ospedale Buccheri La Ferla – Fatebenefratelli**  
*Palermo*

Responsabile Scientifico:  
Dott. **Ignazio Salvatore Brusca**



# **The speaker's declaration with regards to conflict of interest:**

The undersigned **RASO GIUSEPPE**  
as a speaker

pursuant to art. 76 on the Conflict of Interest, paragraph 4 of the State-Regions Agreement of 2 February 2017 and paragraph 4.5. of the National Accreditation Manual for the provision of CME events

**declares**

not to have had financing relationships with subjects with commercial interests in the health field

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## **The ITAMA project and its organisation**

Prof. Giuseppe Raso

Dipartimento di Fisica e Chimica-E. Segrè

Università degli Studi di Palermo





**Project I.T.A.M.A.**

***ICT Tool per la diagnosi di malattie Autoimmuni nell'Area Mediterranea***

*ICT Tools for the diagnosis of Autoimmune diseases in the Mediterranean Area*

**COORDINATOR: Prof. Giuseppe Raso**

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> a research project on celiac disease

> **financed by**  
cooperation programme  
INTERREG Italia-Malta

## **Axis 1 – Research & Innovation**

The improvement of the R&I sector represents one of the main challenges of the cooperation area.

Through Axis 1, the Program intends to strengthen the innovativ capacity of the actors in the cross-border area.

In particular, among the sectors involved, is research applied to human health



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MediCel Project, **2011** (Min Salute) estimated 5 million new celiacs  
by **2020** in the Mediterranean,  
including **1 million children**

**Estimated delay in diagnosing CD: 4 years**

(gastrointestinal symptoms, short stature, anemia, osteopenia, etc.)

Long KH, Rubio-Tapia A, Wagie AE, Melton LJ, Lahr BD, Van Dyke CT, Murray JA.

The economics of coeliac disease: a population-based study. *Aliment Pharmacol Ther* 2010; **32**: 261-269

**Estimated cost of delayed diagnosis of CD: 3,337 euros over 4 years**

(at least 1 hospitalization, 3 visits, 1 specialist visit, 2 cycles of laboratory analyses)

Greco L et al., Celiac burden, *World J Gastroenterology*, 2011 December 7

17(45): 4971-4978, doi:10.3748/wjg.v17.i45.4971

## **>PROBLEM**

The added gastrointestinal symptoms  
and autoimmune complications  
related to delays in diagnosis  
lead to more expensive health care costs

**Is it possible/sustainable to  
anticipate the diagnosis?**



**>OPPORTUNITY**

**collaboration Sicily - Malta**

Specific & Complimentary  
Expertise

- ***autoimmune disease***
- ***ICT to support the diagnosis***

Screening capabilities in  
Malta  
***(20.000 youths)***

***Patient associations are  
present in both countries***



**Define and implement  
Support software tools  
(GUI, DB, DSS)**



**Optimise  
the diagnostic process**

## >OBJECTIVES

- **Support to the doctors**
- **Avoid invasive examination (biopsy) in youths**
- **Reduce NHS costs (early diagnosis)**

**Mass screening:  
Symptom recognition  
+ PoCT  
+ standard serological tests**



**Anticipate and facilitate  
the diagnostic process**



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## >Who is it for?

- Healthcare industry
- Medical professionals
- Population

## Stakeholder

TARGET GROUP	
<i>Healthcare Industry</i>	- <i>Sicily &amp; Malta</i>
<i>Doctors</i>	- <i>Sicily &amp; Malta</i>
<i>Population to be screened</i>	- approx. 20000 Maltese children - approx. 1000 Sicilian subjects

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## Screening

- Screening at schools (**20.000 students Malta**)
- Recovered patients in U.E.D. (**700 in Sicily**)
- Parents of of celiac children (**300 in Sicily**)



## >METHODS

- Screening + conventional test
- ICT

ICT



+



+



=



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## >PARTNERSHIP who does what

PARTNER	TASK	Contact person
Università di Palermo – Dipartimento di Fisica e Chimica ( <b>Capofila</b> )	<b>General coordination; Software development (DB and DSS)</b>	Prof. Giuseppe Raso ( <b>Coordinator</b> )
Università di Messina	<b>Clinical coordination; exams in Sicily; research for diagnostic improvement</b>	Prof. Giuseppe Magazzù ( <b>Scientific Director</b> )
Ministry of Health, Mater Dei Hospital, Malta	<b>Screening in Malta; research for diagnostic improvement</b>	Dr. Christopher Barbara
AcrossLimits, Malta	<b>Software Development (GUI) and Tools for Technology Transfer</b>	Ms. Angele Giuliano

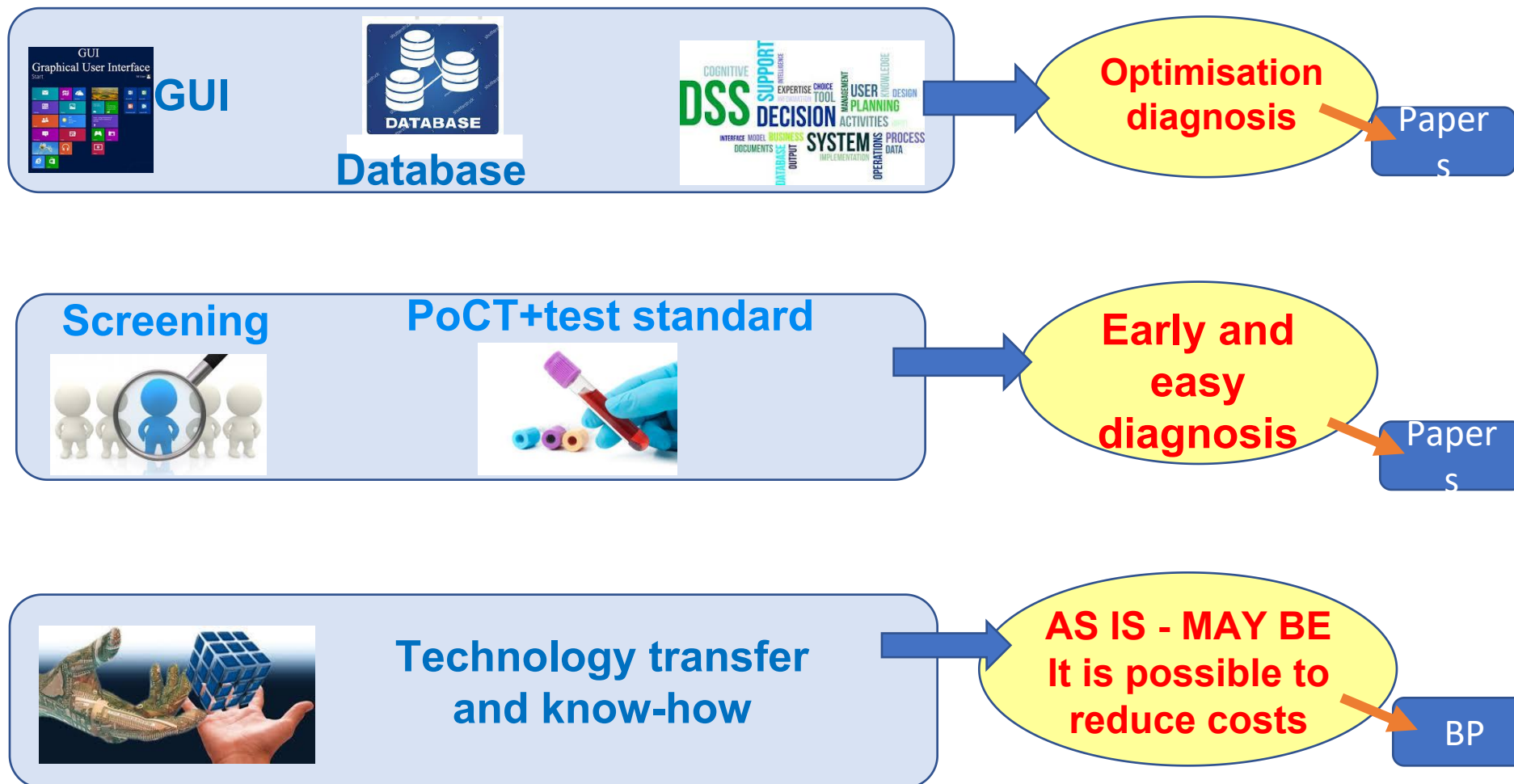
### Collaborations

- DASOE, Assessorato Salute Regione Sicilia, Palermo - partner associaton
- Ospedale Buccheri La Ferla di Palermo

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> results expected and **ACHIEVED**







**> results expected and ACHIEVED**

## **FINAL STATISTICS**

**20665** ***TOTAL subjects registered***  
**20519** ***TOTAL POC Tests performed***  
**141** ***POSITIVE POC tests***  
**20367** ***NEGATIVE POC tests***  
**875** ***BLOOD TESTS performed***  
**165** ***ENDOSCOPIC EXAMINATIONS performed***  
**125** ***CELIACS DIAGNOSED***





**> results expected and ACHIEVED**

- Is POCT reliable? = Easy diagnosis
- How many celiacs have RECOVERED with POCT screening?
- Can a BIOPSY be surmountable? = Easy diagnosis





> results expected and **ACHIEVED**

- Is POCT reliable? = Easy diagnosis

**GOLD STANDARD:** EMA or BIOPSY (448 total subjects)

**TEST:** POCT



- **Sens:**  $a/(a+c) = 94\% \pm 4\%$
- **Spec:**  $d/(b+d) = 96\% \pm 2\%$
- **PPV:**  $a/(a+b) = 91\% \pm 5\%$
- **NPV:**  $d/(c+d) = 97\% \pm 2\%$
- **Accuracy:**  $(a+d)/(a+b+c+d) = 96\% \pm 2\%$
- **Prevalence:**  $(a+c)/(a+b+c+d) = 28\% \pm 4\%$

		DISEASE	
		PRESEN T	ABSEN T
TEST	POSITIVE	a=119	b=12
	NEGATIV E	c=8	d=309



**> results expected and ACHIEVED**

- How many celiacs **RECOVERED** via POCT screening?



*Out of **119** DISCOVERED positives already at POCT and confirmed by EMA or BIO **77** are COMPLETELY ASYMPTOMATIC*

**65%** of CELIACS recovered with an **EARLY DIAGNOSIS**





> results expected and **ACHIEVED**

- Can a BIOPSY be surmountable? = Easy diagnosis

**GOLD STANDARD:** BIOPSY or TGA-IgA>10+EMA (total 274 subjects)

**TEST:** POCT+EMA



- **Sens:**  $a/(a+c) = 97\% \pm 3\%$
- **Spec:**  $d/(b+d) = 99\% \pm 1\%$
- **PPV:**  $a/(a+b) = 99\% \pm 1\%$
- **NPV:**  $d/(c+d) = 98\% \pm 2\%$
- **Accuracy:**  $(a+d)/(a+b+c+d) = 99\% \pm 1\%$
- **Prevalence:**  $(a+c)/(a+b+c+d) = 39\% \pm 6\%$

		DISEASE	
		PRESENT	ABSENT
TEST	POSITIVE	a=105	b=1
	NEGATIVE	c=3	d=165



**> Is it possible/sustainable to  
anticipate the diagnosis?**

Projection of ITAMA results on a cohort of 2,000,000 (not refusing exams)

**AS IS**

Diagnosed cases: **10.000**

Endoscopy and biopsies:  
**4.107**

Sustained costs: **886.250 €**



Costs for delay  
in diagnosis for +18,507 diagnoses:  
**61.756.603 €**



**MAY BE**

Diagnosed cases: **28.507**

Endoscopy and biopsies:  
**718**

Sustained costs: **13.114.936 €**

Costs saved in total (for NHS only) by  
anticipating the diagnosis:

**49.527.917 €**

(social savings would be added to the total, e.g.:  
missed work/school days)

**(Useful to elaborate)**

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> foto





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> photos





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## > ...ITAMA\_CAP Capitalization Project

PARTNER	Contact person
Università di Palermo – Dipartimento di Fisica e Chimica ( <b>Capofila</b> )	Prof. Giuseppe Raso ( <b>Coordinator</b> )
Università di Palermo – Dipartimento PROMISE	Prof. Antonio Carroccio ( <b>Scientific Director</b> )
Università di Enna "KORE"	Prof. Salvatore Sorce
Ministry of Health, Mater Dei Hospital, Malta	Dr. Christopher Barbara

DASOE, Assessorato Salute Regione Sicilia,  
(**Partner Association**)

## Target Groups

<i>Doctors</i>	approx. 300 MMG Sicilia
<i>Population to be screened</i>	approx. 10000 Maltese youths approx. 15000 Sicilian subjects



*Health should be considered as one of the strategic themes for projects dealing with territorial and cross-border development.*

*Projects dealing with health are strategic in three different ways:*

- They improve the quality of life of the inhabitants of the area by tackling common challenges in cross-border regions*
- Where possible they reduce the costs of diagnosis and delayed diagnosis*
- Furthermore, they offer job opportunities to companies in areas that are struggling with diagnostic tools or diagnostic support.*

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***Thank you***