

Opening Presentation from the Paul-Ehrlich-Institut

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Federal Institute for Vaccines and Biomedicines

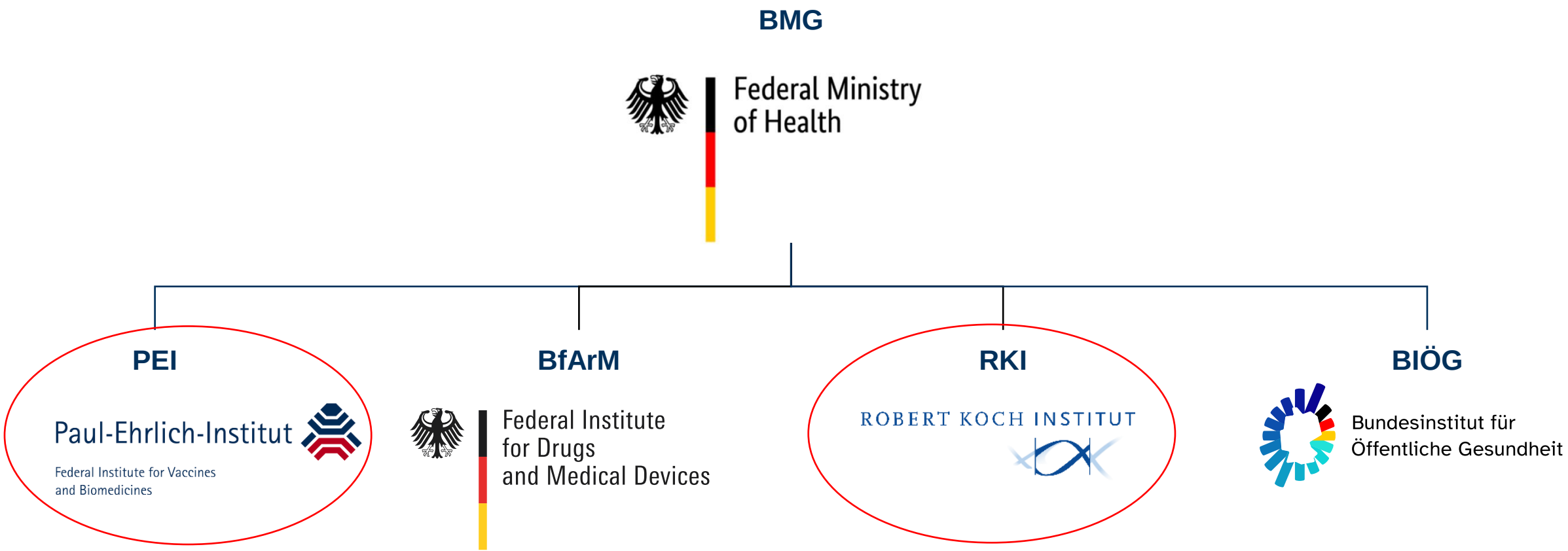
Das Paul-Ehrlich-Institut ist ein Bundesinstitut im Geschäftsbereich des Bundesministeriums für Gesundheit.

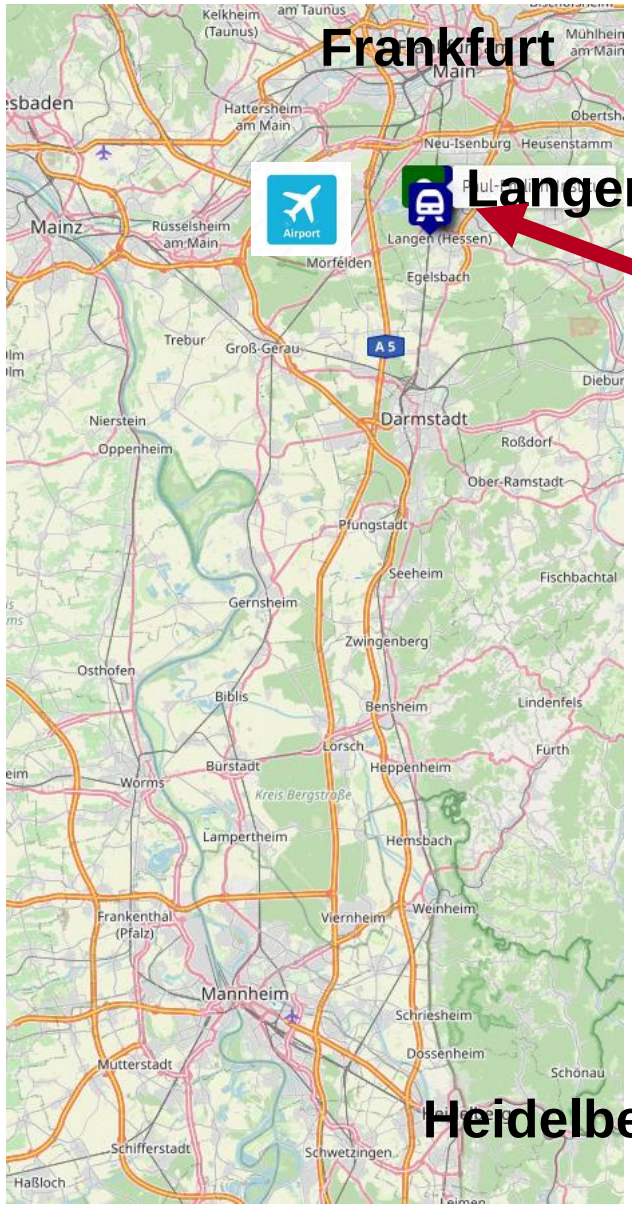
The Paul-Ehrlich-Institut is an Agency of the German Federal Ministry of Health.

Paul-Ehrlich-Institut

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The Paul-Ehrlich-Institut under the umbrella of the Federal Ministry of Health




Frankfurt
Langen
Heidelberg
Airport
Kelkheim (Taunus)
am Taunus
Mühlheim am Main
Hattersheim am Main
Neu-Isenburg
Heusenstamm
Mainz
Rüsselsheim am Main
Langen (Hessen)
Mörfelden
Egelsbach
Trebur
Groß-Gerau
A 5
Darmstadt
Nierstein
Oppenheim
Roßdorf
Ober-Ramstadt
Pfungstadt
Seeheim
Fischbachtal
Gernsheim
Zwingenberg
Osthofen
Biblis
Bensheim
Lindenfels
Lorsch
Fürth
Bürstadt
Heppenheim
Worms
Kreis Bergstraße
Lampertheim
Hemsbach
Frankenthal (Pfalz)
Viernheim
Weinheim
Mannheim
Schriesheim
Dossenheim
Mutterstadt
Schönau
Schifferstadt
Schwetzingen
Haßloch




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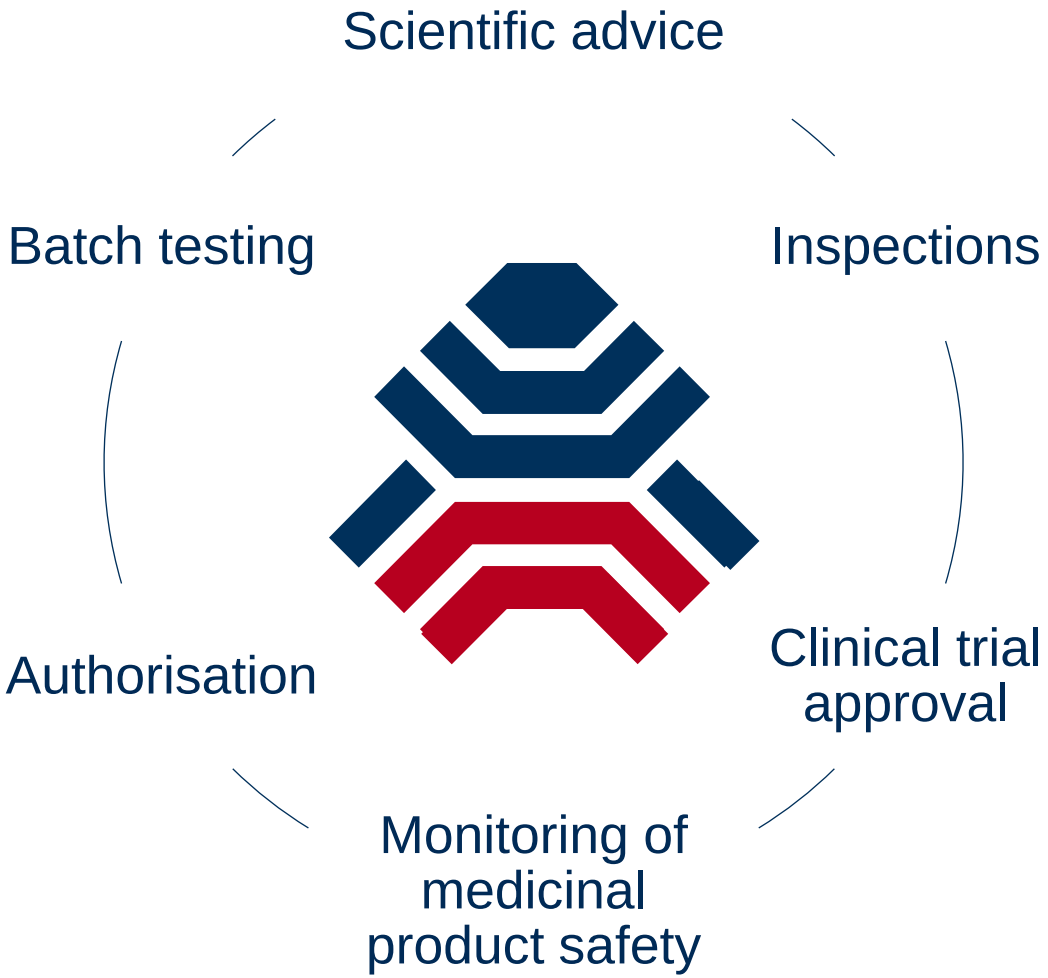
Activities of the Paul-Ehrlich-Institut

1. Regulation of Medicinal Products in remit of PEI
2. In vitro diagnostic medical devices (IVD)
3. Research

Medicinal products within our remit – overview

Vaccines	**Antibodies**	**Advanced Therapy Medicinal Products**
Blood products		**Allergens**
Tissue preparations	**Stem cell preparations**	**Immunological veterinary medicinal products**

Tasks of the Paul-Ehrlich-Institut: Regulation & research in parallel along the entire drug life cycle



- The Paul-Ehrlich-Institut evaluates, tests and monitors medicines along their life cycle.
- The Institute's research ensures it has access to the strong technical expertise required for its regulatory tasks and serves method development (e.g. medicinal product testing).

The European Refence Laboriatories for IVDs (EURL)

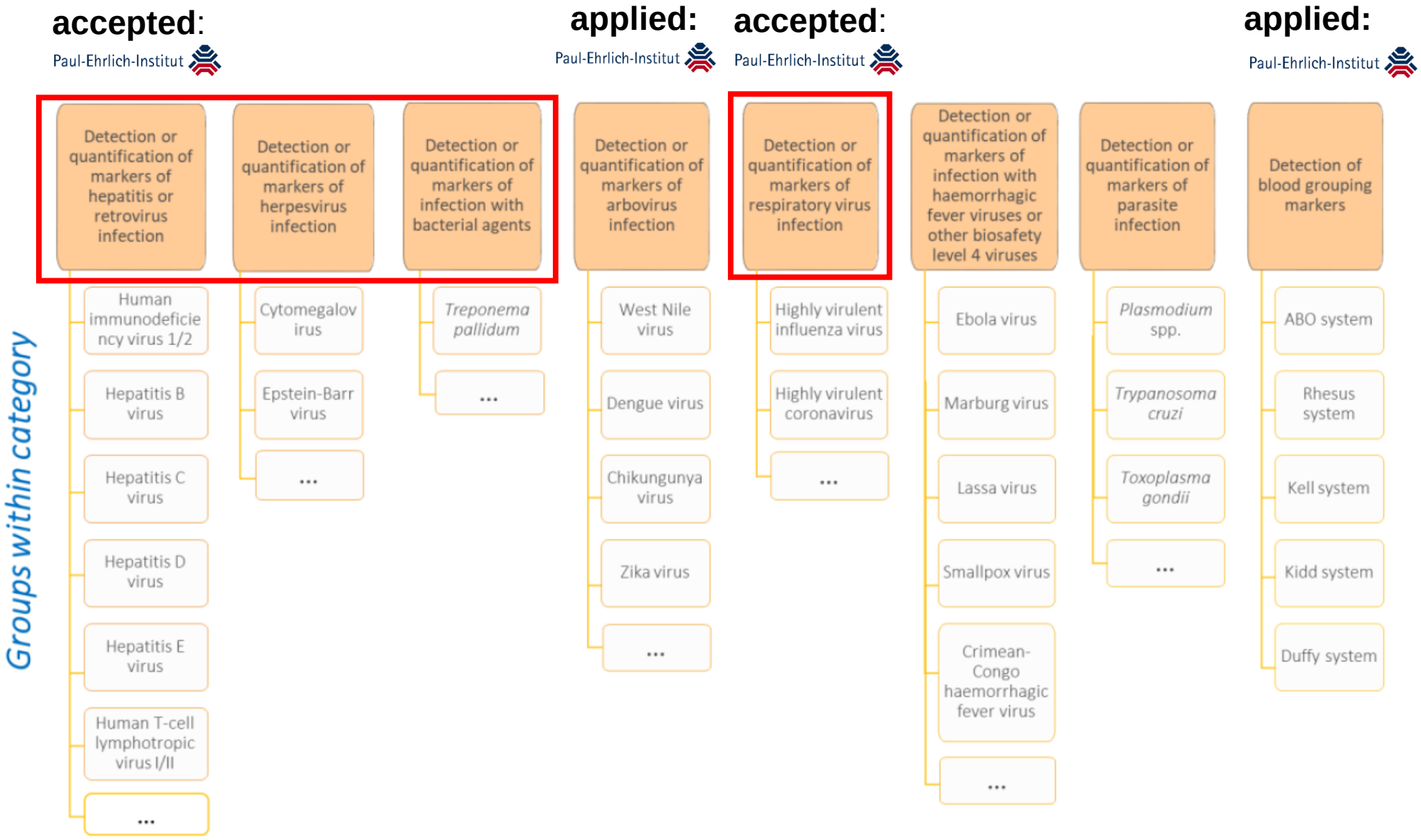
Regulation (EU) 2023/2713

1. RISE Research Institutes of Sweden
2. EURL-IVD at Paul-Ehrlich-Institut
3. SERMAS
4. Instituto de Salud Carlos III
5. Consulting Químico Sanitario SLU



Designation of EURLs for Class D devices

Paul-Ehrlich-Institut



European Commission

EURL-IVD at Paul-Ehrlich-Institut

Paul-Ehrlich-Institut

- IVD testing laboratory (PEI-IVD) under the IVDD 98/79/EC since 2000 for Annex II list A and list B infectious markers (batch testing)
- Accredited according to DIN EN ISO/IEC 17025
- WHO Collaborating Centre for Quality Assurance of Blood Products and in vitro Diagnostic Devices
  - 14 WHO international standards established and made available
- Dossier reviews as part of the WHO program “WHO Prequalification of IVDs” for priority diseases (HIV, HBV, HCV, SARS-CoV-2)
- Reference Lab/participation in interlaboratory comparisons conducted by INSTAND e.V., QCMD and EDQM
- Member in the EU Medical Device Coordination Group (MDCG) working subgroups: standards, new technologies

EURL-IVD at the Paul-Ehrlich-Institut

www.pei.de/eurl-ivd

Paul-Ehrlich-Institut

EURL, IVD
EU Reference Laboratory
Testing Laboratory (PEI-IVD)
Prof. Karin Metzner, MD

WHO Collaborating Centre
for Quality Assurance of Blood Products and IVD Devices
Gabriele Unger, PhD

Section EURL, IVD 1
Serology
Angela Filomena, PhD
+ 4 scientific employees
+ 13 technical employees

Section EURL, IVD 2
Nucleic acid amplification techniques
Marco Straus, PhD (acting head)
+ 4 scientific employees
+ 10 technical employees

Research Topics (non-exhaustive!)

Paul-Ehrlich-Institut

pei.de/research-groups

Infectious diseases: Detection of viruses and bacteria via NGS, microbial safety, virus inactivation

Virus host interactions HIV, bioinformatic applications,

Hematology and cells/tissues endogenous retroviruses and stem cells**,** transposons and genome engineering, xenotransplantation,

Gene Therapy Viral (AAV) and non-viral (LNP) gene transfer, receptor-targeted vectors

Pharmacovigilance data management, viral vaccines, hemovigilance,

immunology, allergology, vet. medicine: …many research topics…

THANK YOU VERY MUCH

FOR YOUR ATTENTION