Preventing Transfusion-Transmitted Malaria

Evaluation of Malaria NAT in France

IFPA – PEI Bilbao – May 2026

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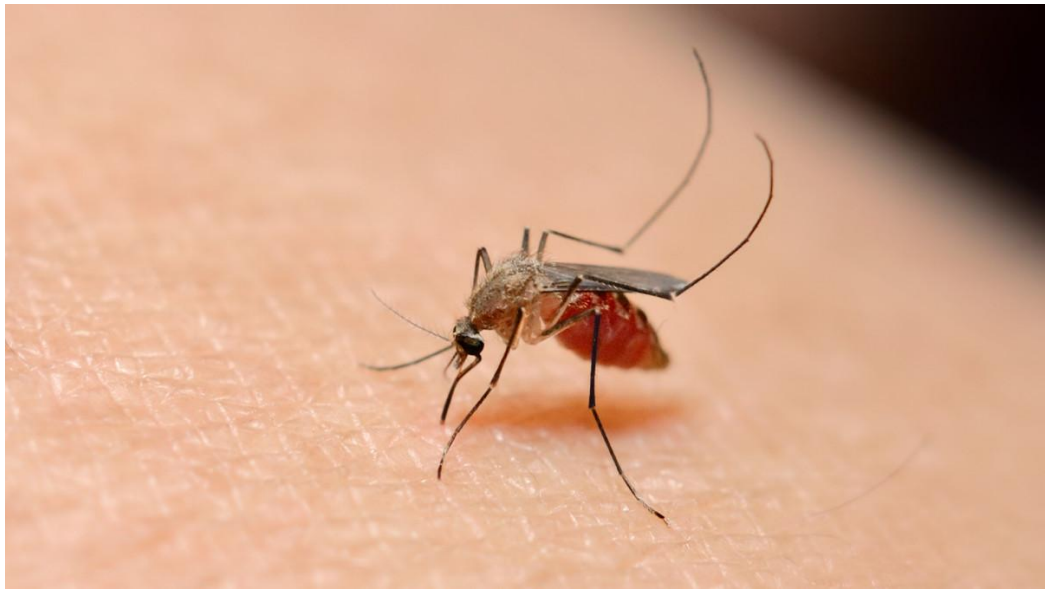
CONFLICT OF INTEREST DISCLOSURE: NONE

OTHER THAN BEING EMPLOYED BY THE ETABLISSEMENT FRANÇAIS DU SANG (EFS), THE FRENCH TRANSFUSION PUBLIC SERVICE.

Malaria and transfusion



- Caused by a parasite (*Plasmodium sp*), transmitted by mosquitos (*Anophele spp*)
- Five species of Plasmodium infect humans: *P. falciparum, P. vivax, P. ovale, P. malariae,* and *P. knowlesi*
- **Because the malaria parasite is found in red blood cells (RBCs), malaria can be transmitted through blood transfusion,** organ transplant, or the shared use of needles or syringes contaminated with blood

Mitigation strategies in Europe

- The risk mitigation for Transfusion-Transmitted Malaria (TTM) is based on a **deferral policy = KEY POINT**
  - In European reglementation, the deferral duration is 3 years after the return from endemic area ! but this duration can be reduced if serological test are used
  - A large number of countries have implemented serological testing which reduced the deferral time and prevented the loss of donation
  - For exemple , In France, deferral duration = 4 month after the return from endemic area

- To date, in non endemic countries, the residual risk is mainly associated to a well **identified high-risk population = donors born in malaria-endemic countries**

  Intensive and repeated exposition to parasite during little childhood led to immuno-tolerance characterized by:

  ✓ low titers of antibodies
  ✓ low and fluctuant parasitemia
  ✓ without any symptoms

  } **RISK +++**
  (because of very low detectability**)**

Current challenges in non-endemic countries

- **Enhance screening sensitivity for the Immuno-tolerant donors to ensure transfusionnal safety**

Serology assay are not very sensitive and can be negative in the case of immuno-tolerant donors .

Ex : in 2 cases of TTM in France in the last 20 years, the donors involved had a negative serology

- **Minimize the loss of blood products**

A positive serology is the proof a past contact with the parasites… but not the proof of a parasitemia into the packed RBC => there is a loss of products with positive serology but which are not really risky

It's a challenge in France for exemple as we have a chronic shortage in some erythocytes phenotypes , especially RH: 1; -2; -3 (R0r)… more than 95% of the donors with this phenotypes are African descendant and many of them are born or travel a lot in Africa !! We destroy each years more or less 2000 packed RBC with this phenotypes because of a malaria positive serology

Laboratory testing solutions

➥Are molecular tests suitable for TTM risk prevention ?

- Main advantage = **very specific** ►avoids loss of donated blood and donors
- Until a few years ago, PCR was not a suitable solution for blood blank because of the lack of sensitivity
- Since 2023 , new tests **adapted on high throughput automated platforms** with very high sensitivity are available (based on amplification of 18S ribosomal RNA (rRNA))

  ex : ≈ 0,003 and 0,005 RBCs parasitized /µL (*IFU Grifols*)

Study DGPalu

Aim

The aim of our study **was to assess the place of the new malaria NAT assay - in the strategy for preventing TTM,** particularly for the detection of infected donors who were born or spent their early childhood in endemic areas.

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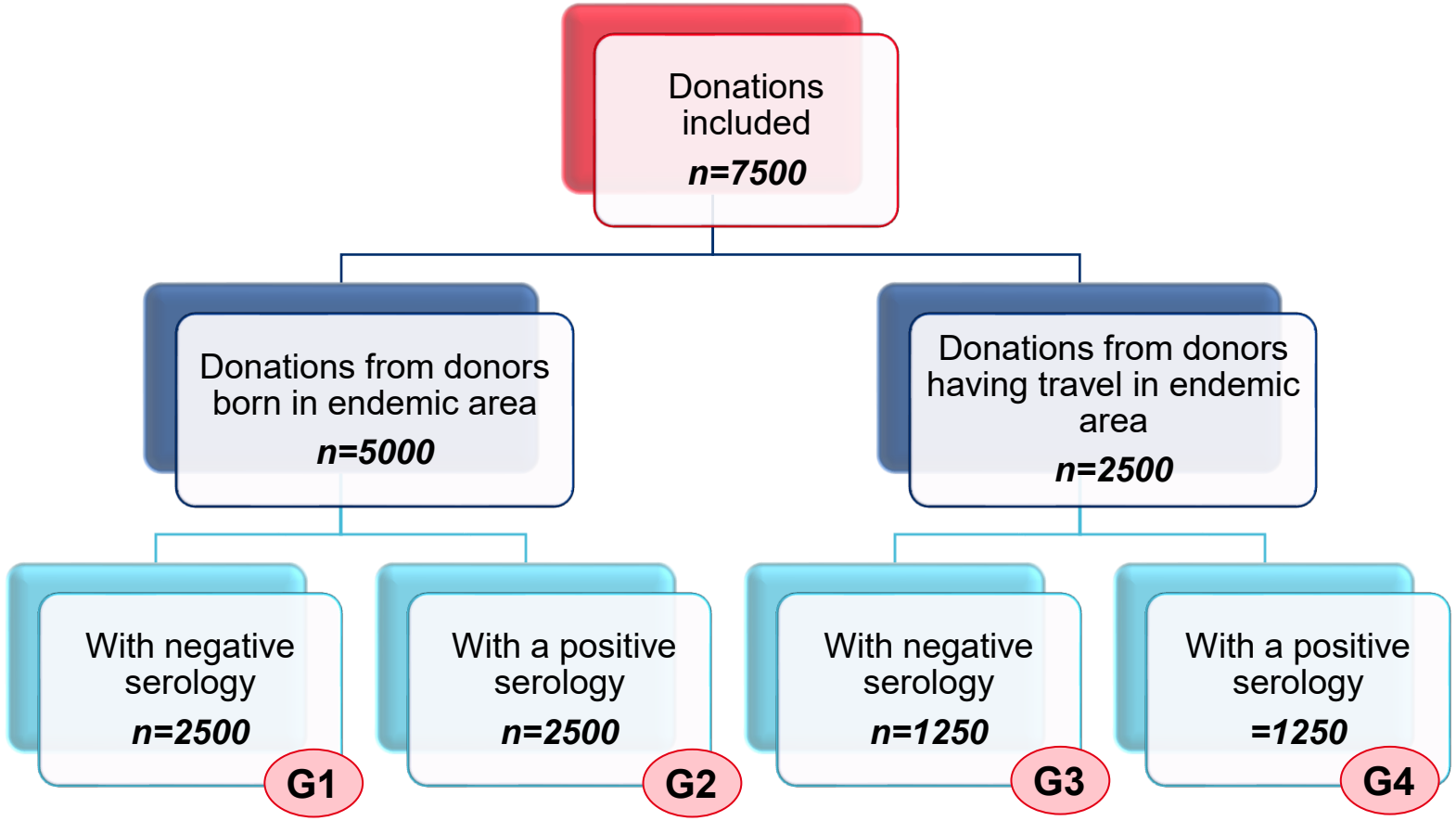
Material and method

- **Inclusions : 7 500 donations** from blood donors collected in Mainland France for whom malaria Ab screening is required for their blood donation



- **Serological testing**
  - Malaria Ab -Diapro
  - Elisa Anti-plasmodium (IgG) – Euroimmun
- **NAT testing**
  - Procleix Plasmodium Assay – Grifols ; performed on the Panther system
  - Cobas® Malaria – Roche ; performed on the Cobas 8800 system

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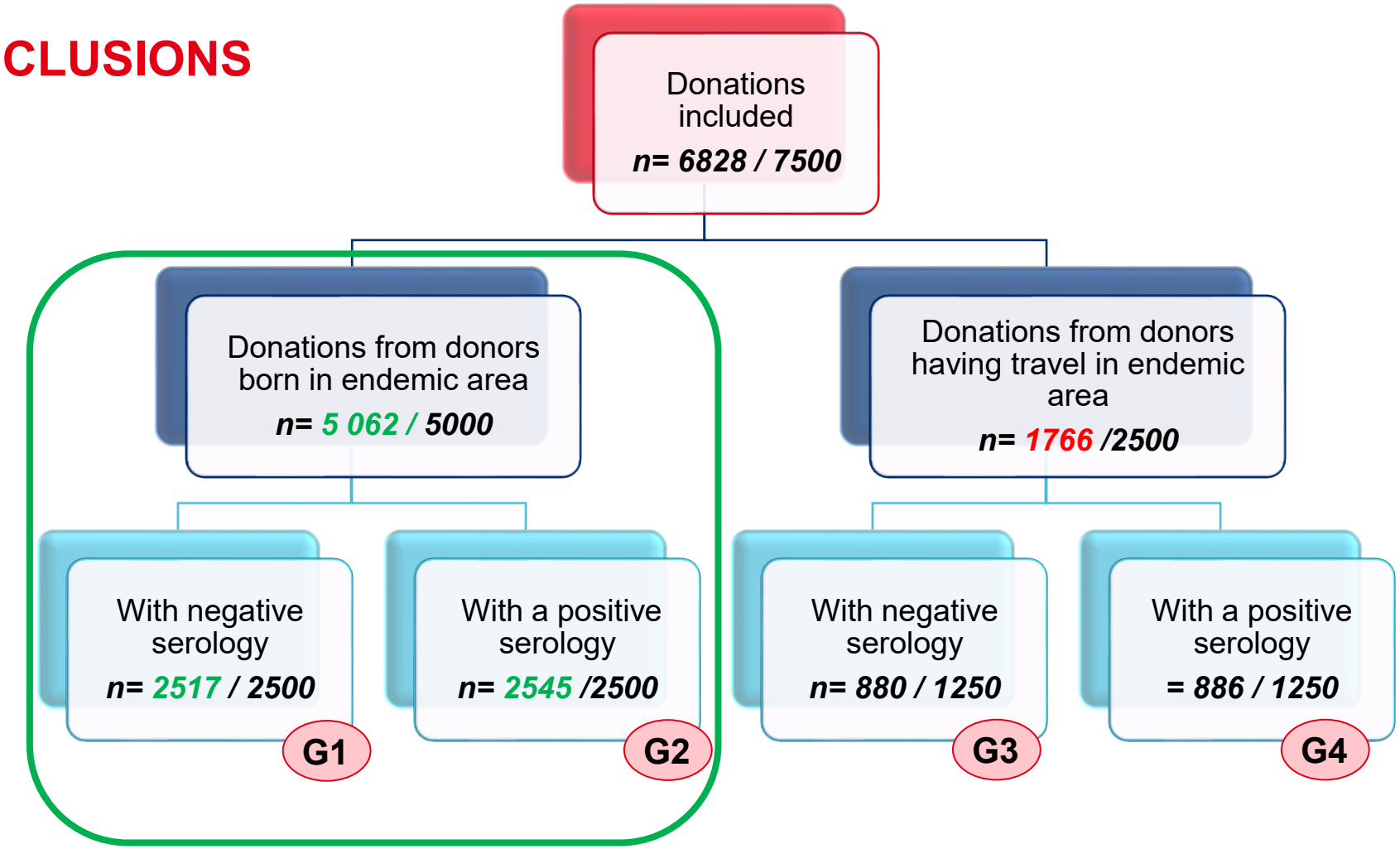
Preliminary results - INCLUSIONS

Study started in june 2024

To date (15th april 2026):

- **6 828 donations included**
- **Arm « donations from donors born in endemic area » => completed**
- **Arm donation from donors having travel in EA => always in process**



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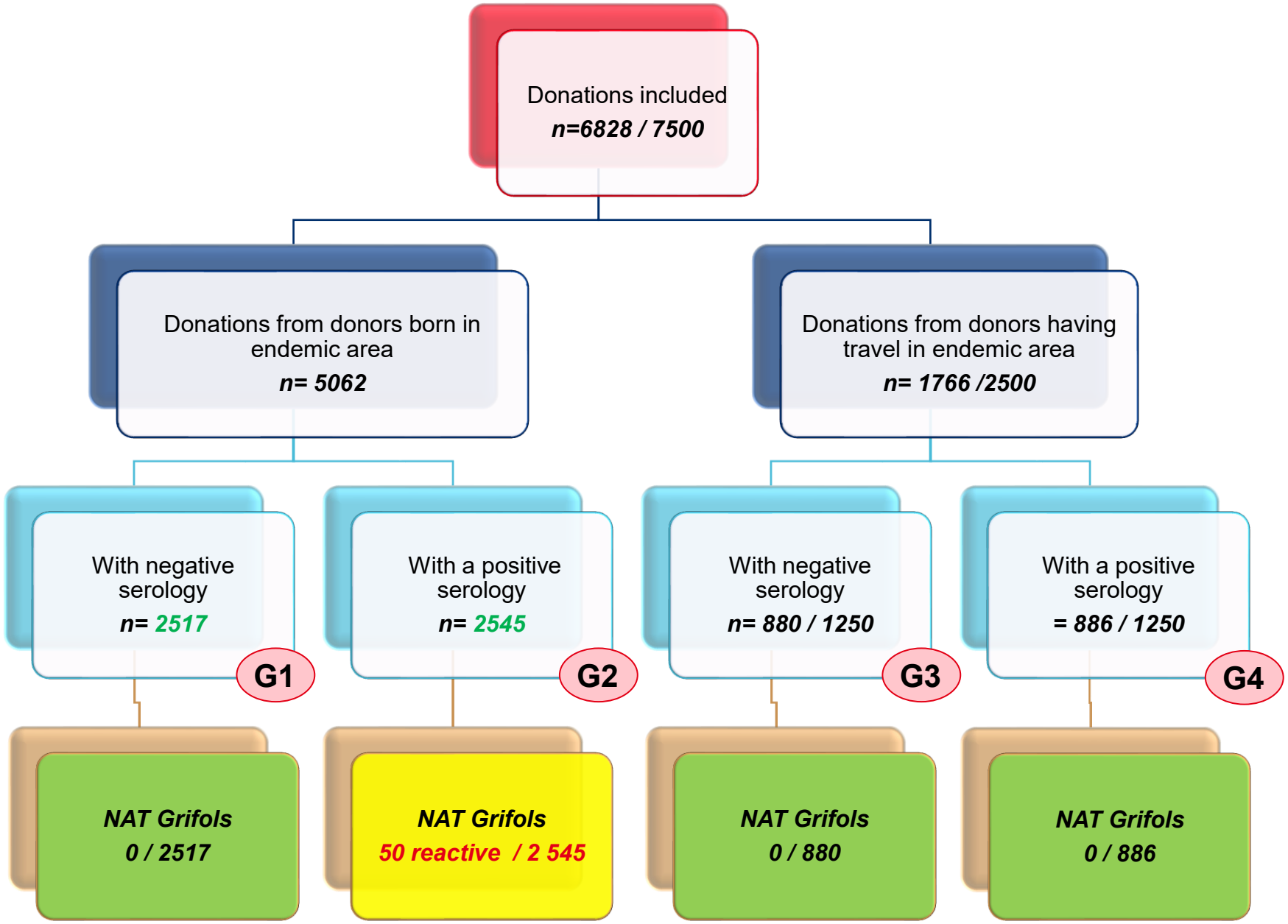
Preliminary results on 15/04/2026

All included donations were tested only by Grifols NAT

Roche NAT: not performed yet



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Preliminary results
FOCUS on G2 sub-group

G2 sub-group = donors native from endemic countries (or having living almost 6 month in endemic area during their little childhood) AND having a malaria positive serology

n = 2 545 donations included

50 REACTIVE with NAT Grifols method (*Procleix Plasmodium Assay , Grifols*)

49 samples confirmed positive with a species diagnosis*

P. Falciparum	**15**
P. Malariae	15
P. Ovale	19

**Confirmation assay and species diagnosis made by Vitalant lab San Diego with the VRI assay wich is a pan-Plasmodium RT-qPCR assay*

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Preliminary results – origins of the 49 NAT positive donations

Birth country of the donor	TOTAL
Angola	1
Benin	1
Burkina Faso	1
Burundi	1
Cameroun	**19**
Congo	2
Cote d Ivoire	**12**
Gabon	2
Guinee	4
Madagascar	1
Mali	1
Rep dem du Congo	2
Republique Centrafricaine	2
Total général	49

All NAT positive donations were from **donors born in Africa** , especially in west Africa (except 1 from Madagascar)

=> In comparison , 41% of the donors / donation included in the arm « born in endemic countries » were born in Africa

zone of birth or of exposition	nb of donations	% in the population included G1+G2
Africa	2099	41%
South and central America	713	14%
Asia	345	7%
Others	1905	38%
Total	5062	100%

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Preliminary results – INFORMATION about the 49 NAT positive donations

Year of arrival in France	n	With malaria crisis reported
2006	1	
2008	1	1
2014	1	1
2015	3	1
2016	1	
2017	2	
2018	1	1
2019	4	2
2021	2	
2022	7	3
2023	8	3
2024	14	8
Data non available	4	
Total général	**49**	**20**

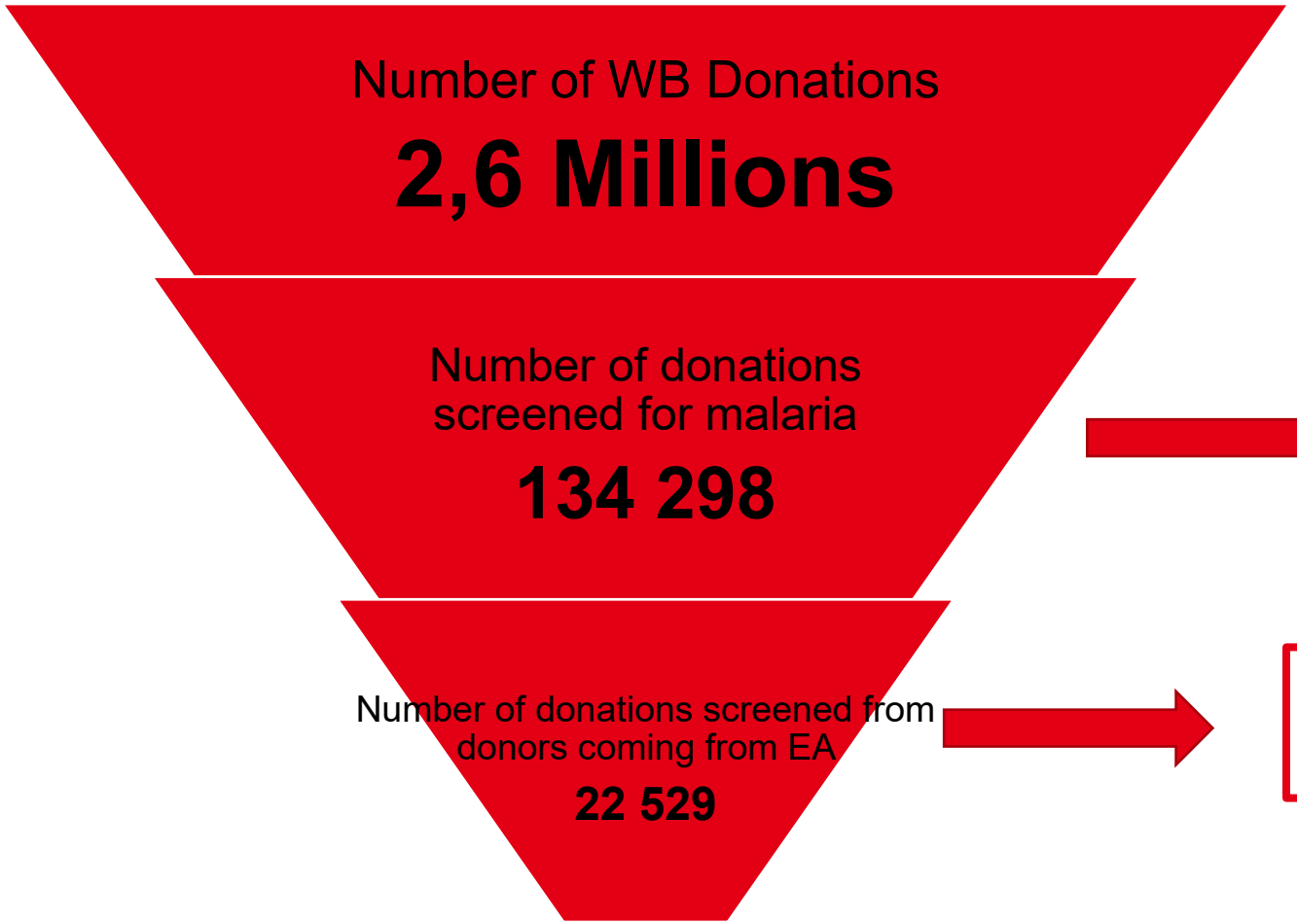
29/49 (59%) of positive donations are coming from donors whom arrived in France less than 3 years before the date of inclusion.

=> The risk decrease with the time

DGPalu – Preliminary lessons learned

- At this stage of the study, the NAT high-sensitivity tests do not demonstrate superiority over serology in terms of transfusion safety (all the NAT REACTIVES sample had also a positive serology)
- Approximately 2% of donors born in malaria-endemic areas who were asymptomatics at the time of donation and test positive in serology are indeed parasitemic **=>>> the risk of TTM is real, but currently under control thanks to the combined deferral policy + serology strategy**
- On the other hand, this means that 98% of donors with a positive malarial serology do not have parasitaemia detectable by current methods **=>> possible excessive destruction of red cells bags**
- 2099 / 5062 donors (from the G1+G2 groups) were born in sub-Saharan Africa (i.e. 41% of the donors of the arm "born in endemic areas"), and represent 69% of the donors of the G2 arm (born in an endemic area with positive malaria serology) **= >> challenge for qualitative self-sufficiency!**

Putting these results into perspective to the real blood donor population in France (2024 activity figures)



5601 positive serology donations
That is 4.17% of the donations tested

4198 positive serology donations
That is 18.6% of the donations tested

2% of 4198 donations tested => by extrapolation, this would represent each year about 80 potentially parasitemic donations in France

Our preliminary conclusions

- **New NAT tests for the detection of Plasmodium sp appear to be highly sensitive**
- **Do not demonstrate at this stage of the study superiority in terms of transfusion safety compared to serology**
- **Confirmed that the very high risk donor population in France are the donors born in Africa**
- **NAT could be a good complement for targeted donor populations (in a balance benefit /risk /cost approach). For exemple:**
  - rare blood donors with a positive malaria serology
  - Or in geographical areas experiencing re-emergence of malaria in order to be able to continue the collection while ensuring transfusion safety

In addition…

- These results are highly relevant in the French context and within our donor population. NAT malaria could really be interesting in specific sub-populations of donors.

- However, **each country must assess its own specific risk profile**, as historical background and immigration patterns may differ, leading to different levels of residual risk.

  For example, in our study, only 14% of donors originate from South or Central America, and only 7% from Asia. Therefore, the conclusions could differ significantly in countries with higher rates of immigration from / travel to these area.

Risk mitigation strategies for TTM should be tailored to each country, taking into account local epidemiology, operational challenges and financial capacities. Deferral policies and screening strategies therefore need to be specifically adapted and carefully evaluated in each setting.

ACKNOWLEDGEMENTS

Etablissement Français du Sang
Dr Marlène Guillet: Operational manager for the study

Dr Valerie Barlet
Dr Claude Maugard
Dr Celine Ricard

Pr Pierre Tiberghien
Dr Pierre Gallian
Dr Syria Laperche

Centre National de Référence pour le Paludisme (APHP Hôpital Bichat)
Pr Sandrine HOUZE

Study *DGVPalu* received a research grant from EBA in 2024

THANK YOU !

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