



the life

OF EFS IN 2019

ANNUAL REPORT
KEY FIGURES



20, avenue du Stade-de-France
93128 La Plaine-Saint-Denis cedex
Tel: +33 (0)1 55 93 95 00
Fax: +33 (0)1 55 93 95 03
www.efs.sante.fr



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The life of EFS in figures

This publication presents the key figures for 2019, illustrating all the activities of EFS and its actors. The key figures concerning donors and donations, blood collections, blood components issued, vigilance reporting, quality control, medical and transfusion biology, research and technology transfer, products for use in laboratories, teaching and research, and the social data report highlight the effectiveness of EFS' operations. Because nothing would be possible without you, the donors, partners, employees, healthcare institutions, blood donor associations and stakeholders, all united to give substance to our raison d'être. *life.*

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The life of our donors

1,610,173

donors in 2019

of which:

1,321,791 known
donors, i.e. 82.09%

288,382 new
donors, i.e. 17.91%

The number of donors (**1,610,173**), for all donation types, is down slightly by **0.82%** compared with the previous year (**1,623,494** donors in 2018).

39.7%

of known donors in 2018 gave blood again in 2019.

Collections per donation type in 2019 (not including granulocytes and autologous)

99,636
Platelets

338,284
Plasma

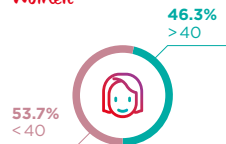


2,487,218
Allogeneic
whole blood

2,925,409

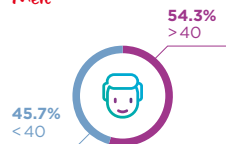
total donations
(all donations including
271 granulocytes)

Women



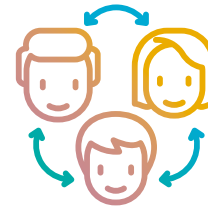
52.6%
women

Men



47.4%
men

PLASMA/ 897,735 LITRES OF PLASMA ISSUED TO THE FRENCH FRACTIONATION AND BIOTECHNOLOGIES LABORATORY (LFB), I.E. +0.9% COMPARED WITH 2018.



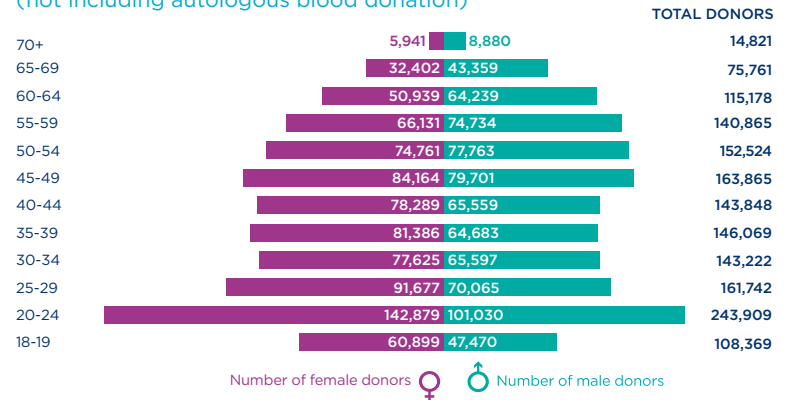
380,716

applicants who did not donate in 2019
(out of 3,306,125 applications),

up
+1.8%
compared with 2018

i.e.
11.52%
of applications

Age pyramid of donors in 2019 (not including autologous blood donation)



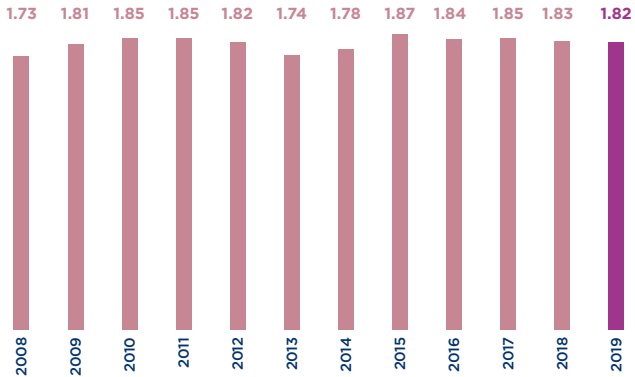
As every year, 20-24 year-olds account for the highest proportion of the donor population (16.88% for women and 13.25% for men, respectively).

This may be explained by blood drives at universities. However, their average annual donation is among the lowest: 1.45% for women and 1.61% for men.

GENEROSITY/ 3.69%, LEVEL OF GENEROSITY (DONORS AS A PROPORTION OF THE POPULATION OF DONOR AGE).

1.82

average number
of donations per donor



1.63

blood donations

2.59

plasma donations

2.39

platelet donations

i.e.

2,925,409

collections from a total of

1,610,173 donors

Average number of donations:

1.92

for known donors and

1.33

for new donors

COLLECTION/ 53, AVERAGE NUMBER OF DONATIONS PER MOBILE COLLECTION UNIT.

MOBILE COLLECTIONS



1,971,968

donations in 2019

of which:

1,971,919

Whole blood

49

Plasma

FIXED SITES

(not including granulocytes)



953,170

donations in 2019

of which:

515,299

Whole blood

338,235

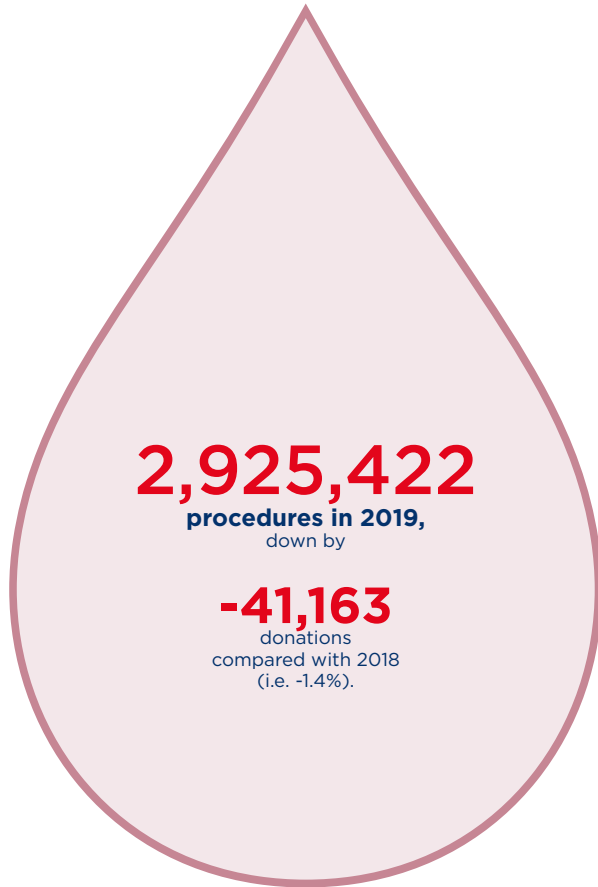
Plasma

99,636

Platelets

Compared with 2018, a reduction in collections of whole blood was observed in 2019, essentially from mobile collection units. Collections from fixed sites increased slightly, in line with EFS' global strategy.

Donations that save lives



FOCUS/ 2019 COLLECTIONS, DOWN COMPARED WITH 2018, EXCEPT IN THE CASE OF AUTOLOGOUS COLLECTIONS (+33%) AND APHAERESIS COLLECTIONS OF RBCC/APC/PLASMA (+12.4%).

DONATIONS OF WHOLE BLOOD

2,487,230
procedures in 2019

A decrease of -1% compared
with 2018.

Of which

2,487,218
allogeneic
collections
(-1%)

And

12
autologous
collections
(+33%)

APHAERESIS DONATIONS

438,192
collections in 2019

A decrease of -3.4% compared with 2018.
There is a contrasted evolution from one
donation type to the other.

339,265 simple
aphaeresis
(down 1.5% due to the
reduction in plasma
collections)

98,927 combined aphaeresis
(down 9.5% due to the
reduction in "APC/
plasma" aphaeresis)

Of which

Plasmapheresis:
338,284 (-1.5%)

APC/plasma:
96,137 (-10%)

Platelet aphaeresis:
710 (-13.9%)

APC/RBCC:
81 (-8%)

Granulocytes:
271 (-18.9%)

RBCC/APC/plasma:
2,709 (+12.4%)

Quality control of our LBP

Red blood cell concentrates (RBCC)

Their active ingredient is haemoglobin. The RBCC must contain at least 40g of haemoglobin (Hb).

55.9g

The average haemoglobin content of the RBCC prepared by EFS in 2019, with a compliance rate of:

99.4%

Aphaeresis platelet concentrates attenuated to pathogenic agents by Intercept treatment (APC-IA)

Their active ingredient is the total quantity of platelets. APC-IA must contain at least 2.0×10^{11} platelets.

4.5 x 10¹¹

platelets, the average platelet content of the APC-IA prepared by EFS in 2019, with a compliance rate of:

99.8%

Pooled platelet concentrates attenuated to pathogenic agents by Intercept treatment (PPC-IA)

Their active ingredient is the total quantity of platelets. PPC-IA must contain at least 2.0×10^{11} platelets.

3.5 x 10¹¹

platelets, the average platelet content of the PPC-IA prepared by EFS, with a compliance rate of:

100%

Residual leucocyte content in cellular LBPs

In terms of leucocyte reduction, the minimum percentage of compliant units stipulated by regulations is:

97%

All of the RBCC, APC-IA and PPC-IA prepared by EFS are compliant with these requirements.

Therapeutic plasma (Q-AFFP and Q-FFP, FFP-IA and pooled FFP-IA)

Factor VIII and fibrinogen
The methods for testing and the standards applicable to FFP for FVIII and fibrinogen vary according to the plasma manufacturing method used. For FFP-IA and pooled FFP-IA, the minimum

requirement for FVIII is **0.5 UI/ml** for a minimum of **70%** of controlled units and **2 g/l** fibrinogen for a minimum of **70%** of controlled units. All of the FFP-IA prepared by EFS is compliant with these requirements. As regards the plasma safeguarded by a 60-day quarantine (Q-AFFP and Q-FFP), the minimum requirement for FVIII is **0.7 UI/ml**. All of the quarantined FFP prepared by EFS is compliant with these requirements.

Residual leucocyte content
In terms of leucocyte reduction for therapeutic plasmas, the minimum percentage of compliant units stipulated by regulations is:

95%

All of the FFP prepared by EFS is compliant with these requirements.

LBP issuing

146

EFS sites ensure the supply of labile blood products (LBP) throughout mainland France.

Of which
139 help
distribute to
blood banks



1,500

health care
institutions served



619

banks, 197 for
vital emergency

24/7

Most EFS issuing sites serve health care institutions, and therefore patients, to whom they deliver 24 hours a day 7 days a week and provide transfusion advice.

Units of blood components issued by EFS in 2019



2.9 million
products issued

RED BLOOD CELL CONCENTRATES (RBCC) ISSUED

-0.5%

fewer units of RBCC issued in 2019 compared with 2018.

In 2020, EFS implemented reinforced qualitative and quantitative monitoring of the increasing needs of patients for LBP.



PLATELETS ISSUED

-5.3%

fewer units of platelets based on quantity of active ingredient (QAI) issued in 2019 compared with 2018.

+4.9%

units of pooled platelet concentrates (PPC) originating from donations of whole blood issued.

66.9%

The proportion of PPC issued as a proportion of platelets issued, compared with 63.7% at the end of 2018.

-8.9%

fewer units of aphaeresis platelet concentrates (APC) issued.

Medical and transfusion biology



491 million

biomedical analysis value units.

This is the medical biology activity carried out by EFS in 2019, i.e. a +1.1% increase compared with 2018.

RCI

68%

of these tests vital to the transfusion of patients concerned red cell immunohematology (RCI).

VBMD

17,103

volunteer

bone marrow donors (VBMD) registered in EFS centres in 2019, i.e. a 10% increase on 2018,

and 5,091

in mixed VBMD centres (CHU (university hospitals)/EFS).

HLA

157 million

biomedical analysis value units were carried out in 2019 by histocompatibility and immunogenetics laboratories, which perform biological testing associated with the HLA system. This figure is up by +3.9% compared with 2018.

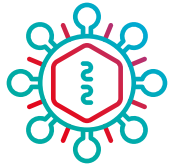
15

HLA sites in mainland France contribute to the treatment of patients undergoing transplantation. The majority are volunteer bone marrow donor centres and have contributed towards enriching the French Bone Marrow Transplant Registry kept by the Agency of Biomedicine (ABM).

Cell therapy activities

KNOW-HOW/ CELL THERAPY ACTIVITIES AND THE DEVELOPMENT AND PRODUCTION OF ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPs) AND TISSUE BANKS ARE DISTRIBUTED ACROSS 9 REGIONAL ESTABLISHMENTS.

EFS IS MADE UP OF



17

cell therapy units



8

tissue banks.
In 2019, they issued:

9,214 units
of tissue (not including skin)

189,169 cm²
of skin

6,333 cells



5

advanced therapy (ATMP)
pharmaceutical platforms

Our research and technology transfer

RESEARCH AT EFS

112 dedicated full-time equivalents,
(FTEs) across 19 teams

€11.65M budget
214 publications
in peer-reviewed journals

51 clinical research projects
ongoing in 2019,
16 of which sponsored
by EFS

TECHNOLOGY TRANSFER

5

licensing agreements/
licensing options on
patents signed with
industrial partners

7 new priority requests
for patents filed in 2019

9 prior art studies
performed. Prior art
studies enable us to
check whether an
invention fulfils the
conditions for obtaining
a patent in terms of
innovation

16 technologies
promoted with the aim
of technology transfer

58

patent families in the
EFS portfolio

Breakdown of patent families in the EFS portfolio

9%
Production
process

17%
Medical
device

32%
Therapeutic

9

declared inventions

6%
Safeguarding
production

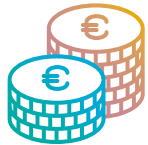
17%
Diagnostic

19%
Other



Our reagent production unit

IVDMD/ THE IN VITRO DIAGNOSTIC MEDICAL DEVICES WERE MANUFACTURED BY THE REAGENT PRODUCTION UNIT (RPU), AT 6 MANUFACTURING SITES, DISTRIBUTED OVER 5 REGIONAL ESTABLISHMENTS.



These generated
7.8 million
euros of the RPU's turnover,
an increase of 16% compared with 2018.



70
product references,
30 of which have a CE label.



54%
the proportion of turnover
of total activity generated from external clients,
up on the previous year (46% in 2018).

PLTR activity

The PLTR services (products for use in laboratories, teaching and research) form part of the establishment's public health mission by providing blood products that are indispensable for teaching and scientific progress. These donations, which are not directly for transfusion purposes, represent an alternative for many prospective donors who are permanently deferred, or for first-time donors who have temporary contraindications to blood donation.

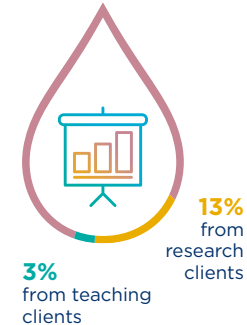
In 2019, PLTR activity accounted for a turnover of

€8,925K
from

466 key
external client accounts

Breakdown of turnover

84%
from industrial clients
in the diagnostic or
pharmaceutical sector



400,000
products issued in total.

Moreover, the PLTR teams make the necessary blood products available to internal analytical and research laboratories within EFS, in addition to the reagent production unit (RPU).

47 FTEs

distributed throughout the establishments provide non therapeutic blood products to educational institutions and for research.

3 EFS regional establishments

Auvergne - Rhône-Alpes, Centre - Pays de la Loire and Hauts-de-France - Normandie are ISO 2001 : 2015 certified for PLTR, and have dedicated teams capable of responding to "customised" specifications. All the plasmas and serums not used in the other establishments are centralised at the Hauts-de-France - Normandie EFS regional establishment, where specific screening tests allow starting materials to be proposed that are negative or positive for certain markers.

Health care centres full of life

EFS is made up of

62 health care centres

(HCCs) across the regional establishments.

The HCCs carry out

4 important activities:

bloodletting procedures, cell collection, therapeutic aphaeresis and transfusions.

IN 2019, THEY PERFORMED

37,501

bloodletting procedures on patients suffering from haemochromatosis or other iron overload diseases.

2,283

collections of autologous blood haematopoietic stem cells (HSC) and 367 allogenic, in addition to 105 donations of mononuclear cells and

3,491 extracorporeal photopheresis procedures (ECP).

4,981

aphaeresis procedures (not including HSC), a decrease of 33% compared with 2018, with

2,619 plasma exchanges and

2,362 red cell exchanges

2,307

transfusions

CELL THERAPIES/ EFS HAS 62 HCCs, 8 OF WHICH ARE APPROVED BY THE LABORATORIES FOR THE DONATION OF PRECURSOR CELLS OF CAR T-CELLS.

OTHER THERAPEUTIC PROCEDURES

The HCC teams mainly receive patients on an outpatient basis, but they also travel to health care establishments where necessary. In 2019, the aphaeresis procedures carried out outside the health care centres have seen a huge increase: 1,133 procedures (compared with 521 in 2018) were performed, especially in the case of paediatric treatments (children under 20 kg).



282
depletions
of lipids or
red cells



26
depletions
of white cells

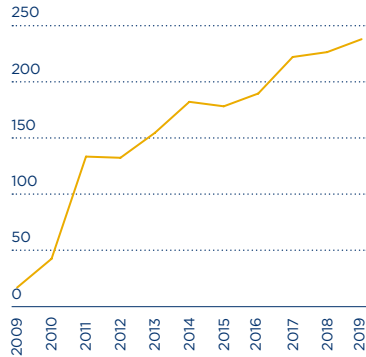
CAR T-CELLS: PROMISING NEW CELL THERAPIES

These use the patient's own T lymphocytes, genetically modified to fight tumour cells. The HCCs intervene in this treatment by collecting the patient's mononuclear cells (MNC). In 2019, **8 CAR T-cell-approved health care centres** performed **201 CAR T-cell collections**.

These types of collection rose sharply compared with the 60 donations performed in 2018. Once collected, the cells are shipped (via cell therapy and tissue engineering banks) to the USA, where the genetic modification is performed. The medicinal product thus obtained is returned to the patient for injection. The current indications for this treatment are blood disorders (acute and chronic leukaemias), but could be extended to solid tumours (glioblastoma, cancer of the ovaries, etc.).

Vigilance reporting to save lives

SDAE* 2011-2018 - INDICATORS PER 100,000 DONATIONS



*Severe Donor Adverse Events, grades 2, 3, 4 and imputabilities 1, 2, 3, NE.

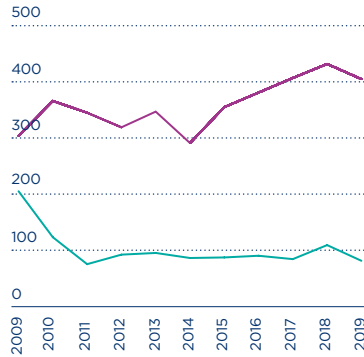
Severe Donor Adverse Events (SDAE):

vasovagal reactions still in the foreground

The number of SDAE per 100,000 donations is increasing, rising from 221 in 2018 to 228 in 2019.

Vasovagal reactions still account for the greatest proportion of these SDAE, at **83.73%**.

NUMBER OF RAE WITH STRONG IMPUTABILITY



■ Grades 3, 4 ■ Grades 2, 3, 4

Recipient Adverse Events (RAE)

The number of RAE reported is constant: 9,175 in 2019 (all severities and all imputabilities combined, of which 8,869 investigations are closed), compared with 9,219 in 2018 (of which 8,966 investigations are closed).

FOCUS/ ON TRANSFUSION-TRANSMITTED BACTERIAL INFECTIONS (TTBI), NO TTBI IMPUTABLE TO A TRANSFUSION OF PLATELET CONCENTRATES HAS BEEN OBSERVED (GENERALISATION FROM IA-PC IN NOVEMBER 2017); IN CONTRAST, ONE CITROBACTER FREUNDII TTBI WHICH WAS ATTRIBUTED WITH CERTAINTY TO A TRANSFUSION OF RBCC WAS NOTED.

Two deaths are attributable to transfusion (compared with three in 2018)

The two deaths were caused by acute pulmonary oedema overload in the context of transfusion of two units of RBCC in elderly patients, one of whom presented with an underlying cardiovascular disorder. In one of the cases, the inter-transfusional time delay was not complied with: the two units of RBCC were transfused one after the other, triggering the APO overload.

Serious Adverse Events (SAE) in the transfusion chain

1,083 SAE were reported on the e-FIT IT system in 2019, of which **273 occurred at EFS (versus 1,159 in 2018, of which 357 occurred at EFS)**. Of the 273 reports, 114 relate to the collection stage (versus 167 in 2018) and 100 the distribution/issuing stage (versus 143 in 2018). The notable decrease in the number of SAE reported in 2019 (as in 2018) is associated with the change in reporting methods for SAE from "collections of excessive volumes of whole blood", which, since 2 January 2018, are no longer reported on the e-FIT IT system (for events occurring in 2018) but via a new reporting arrangement in compliance with the ANSM (French National Agency for Medicines and Health Products Safety).



Medical device vigilance

167

reports in 2019 compared with 146 in 2018



Reagent vigilance

18

reports in 2019 compared with 13 in 2018



Biovigilance

145

reports in 2019 compared with 118 in 2018

Our social data report

9,689

people at EFS
on 31 December 2019

369
personnel made
available from
the public sector

8,555
private-law
employees



5
contracted
public servants

708
temporary
workers

52
seconded
from public
service

72.6%

women

70.6%
of staff involved
in an activity in
the transfusion
chain

43
average age

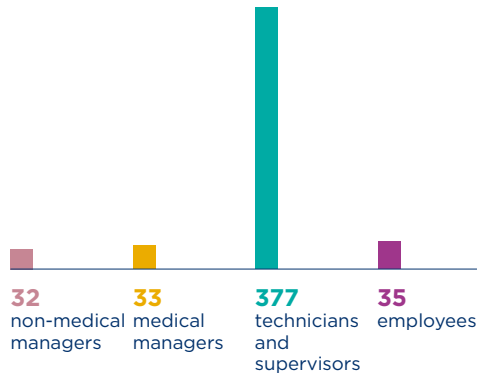
13
average years of
service

477
disabled
workers

on 31 December 2019,
which represents
for each
socio-professional
category:

7.6%

the employment rate
of disabled workers in
2019



HUMAN RESOURCES/ THE PERSONNEL IN OUR "CORE BUSINESS" ACTIVITIES OF RESEARCH AND SUPPORT.

682

hires on permanent
contracts

of which

167

hires aged under 26:

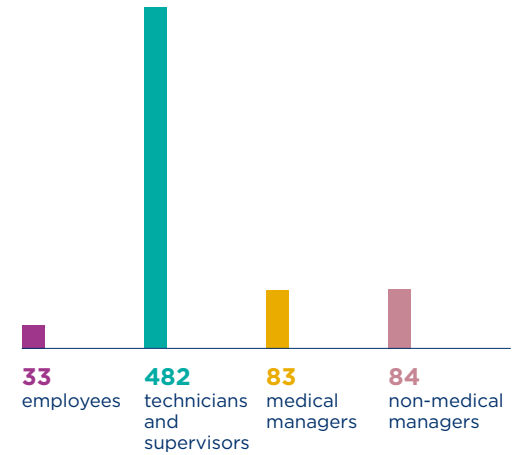
8 employees

151 technicians
and supervisors

8 non-medical
managers

597

departures



22.4%

of employees are
part-time,
which represents
for each socio-
professional category:

