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INNOVATIVE PARTNERSHIP
FOR ACTION AGAINST CANCER

Genomics - opportunities and obstacles

iPAAC WP6 Genomics and Cancer

Marc Van den Bulcke – Cancer Centre – Sciensano - Belgium

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THREE TOPICS

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1. Implementation of NGS in routine diagnostics in oncology at national level

2. Genomics and Ethics

3. PCP for sustainable development of complex NGS application in Healthcare Systems

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IMPLEMENTATION OF NGS IN ROUTINE DIAGNOSTICS IN ONCOLOGY IN BELGIUM (2016-2020)

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Roadbook	
ACTION 1	Establish a commission: Commission Personalized Medecine (ComPerMed)
ACTION 2	Development of guidelines for NGS use in (hemato)-oncology
ACTION 3	Development of criteria for NGS use in (hemato)-oncology
ACTION 4&5	Develop and organize a benchmarking trial and EQA for NGS use in (hemato)-oncology
ACTION 6	Implement NGS registration, storage and data management
ACTION 7	Provide NGS education and training
ACTION 8	Informed consent, legal and ethical implications of NGS use in (hemato)-oncology molecular diagnostics
ACTION 9	Pilot study 'NGS use in routine diagnostics'
ACTION 10	Build on hospital networks for NGS use in (hemato)-oncology

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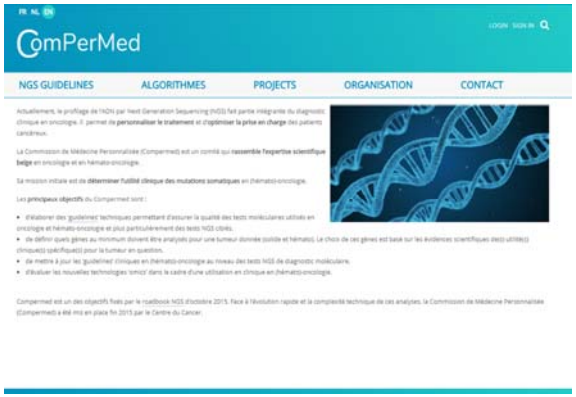
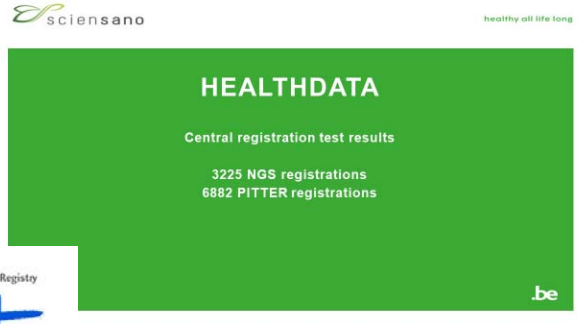

ComPerMed
NGS GUIDELINES
ALGORITHMES
PROJECTS
ORGANISATION
CONTACT


BJMO PRACTICE GUIDELINES 57
The Belgian next generation sequencing guidelines for haematology-oncology
A. Hébrant, Ir, PhD[1], G. Froyen, PhD[2], B. Maes, MD, PhD[2], R. Salgado, MD[3], M. Le Mercier, PhD[4], N. D'Haene, MD, PhD[5], S. De Keersmaecker, PhD[1], K. Claes, PhD[6], J. Van der Meulen, PhD[7], P. Aftimos, MD[1], J. Van Houdt, PhD[8], K. Cuppens, MD[9], K. Vanneste, PhD[2], E. Dequeker, PhD[8], S. Van Dooren, PhD[10], J. Van Huysse, MD[11], F. Nollet, PhD[12], S. van Laere, PhD[13], B. Denys, MD[12], V. Ghislain, PhD[14], C. Van Campenhout, PhD[14], M. Van den Bulcke, PhD[7]

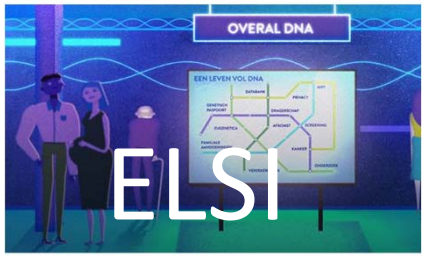

BELAC


sciensano
RAPPORT GLOBAL DEFINITIF
Next Generation Sequencing (NGS)
Case studies
Tumeurs solides
2019/1
.be

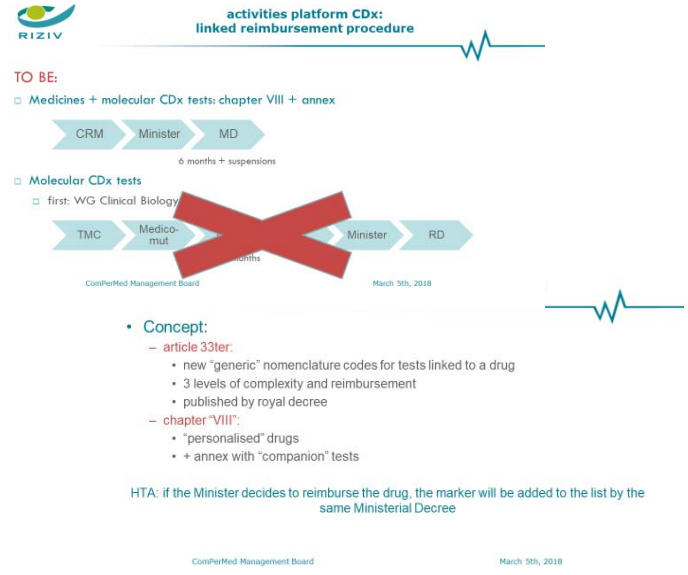
GOVERNANCE

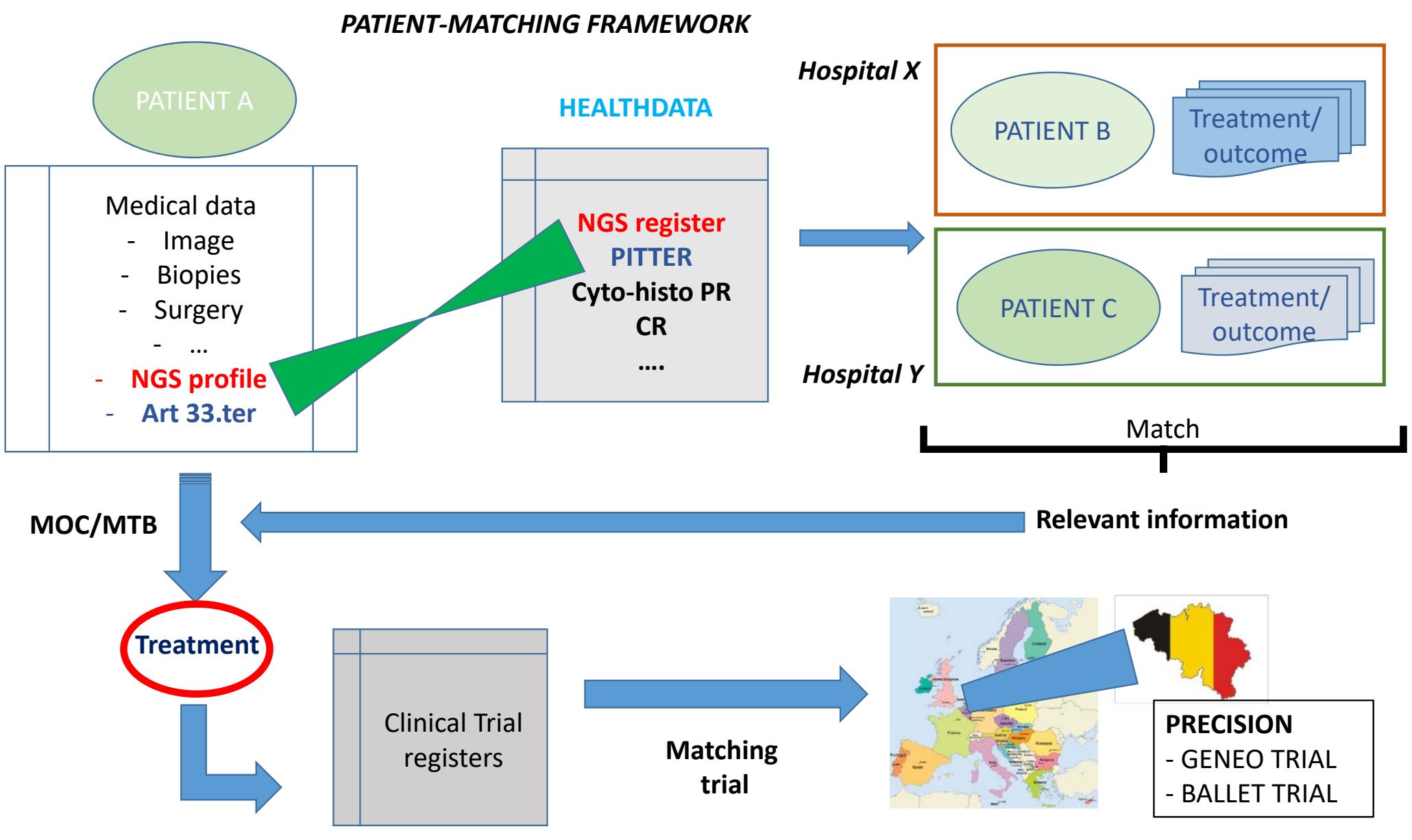

sciensano
healthy all life long
HEALTHDATA
Central registration test results
3225 NGS registrations
6882 PITTER registrations
.be


Belgian Cancer Registry


OVERAL DNA
EEN LEVEN VOL DNA
ELSI


BELGIUM
NETHERLANDS
GERMANY
FRANCE
LUXEMBOURG
Zeebrugge
Knokke
Blankenberge
Ostend
Veurne
Diksmuide
Ypres
Mouscron
Tournai
Verviers
Hautes Fagnes NP
Bastogne
OVEREENKOMST IN TOEPASSING VAN ART 56, § 1 TER FINANCIERING VAN EEN PILOOT-STUDIE BETREFFENDE DE GECONTROLEERDE INTRODUCTIE VAN NEXT-GENERATION-SEQUENCING IN ROUTINE DIAGNOSTIEK IN ONCOLOGIE EN HEMATO-ONCOLOGIE
01 july 2019


RIZIV
activities platform CDx:
linked reimbursement procedure
TO BE:
Medicines + molecular CDx tests: chapter VIII + annex
CRM
Minister
MD
6 months + suspensions
Molecular CDx tests
first: WG Clinical Biology
TMC
Medico-mut
Minister
RD
ComPerMed Management Board
March 5th, 2018
Concept:
article 33ter:
new "generic" nomenclature codes for tests linked to a drug
3 levels of complexity and reimbursement
published by royal decree
chapter "VIII":
"personalised" drugs
+ annex with "companion" tests
HTA: if the Minister decides to reimburse the drug, the marker will be added to the list by the same Ministerial Decree
ComPerMed Management Board
March 5th, 2018


PATIENT-MATCHING FRAMEWORK
PATIENT A
Medical data
- Image
- Biopies
- Surgery
- …
- NGS profile
- Art 33.ter
HEALTHDATA
NGS register
PITTER
Cyto-histo PR
CR
….
Hospital X
PATIENT B
Treatment/ outcome
PATIENT C
Treatment/ outcome
Hospital Y
Match
MOC/MTB
Relevant information
Treatment
Clinical Trial registers
Matching trial
PRECISION
- GENEO TRIAL
- BALLET TRIAL

GENOMICS AND ETHICS

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Policy paper ‘Public Health Genomics and Cancer’

WP6: ELSI

- Focusgroup studies
- Surveys
- Citizenforum
- Online DNAdebat

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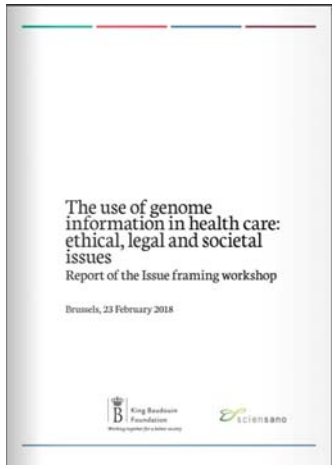

sienna.

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DNA ADN
DEBAT

SOCIETAL DEBATE: WHY?

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- Support
  - No genomics without consent, trust, data sharing
- Value laden
  - Genetics, medical research, privacy, … - ELSI
- Good governance
  - Taking the perspective of citizens into account

➢ Many questions, no easy solution

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WICKED PROBLEMS AND SOCIETAL DEBATE

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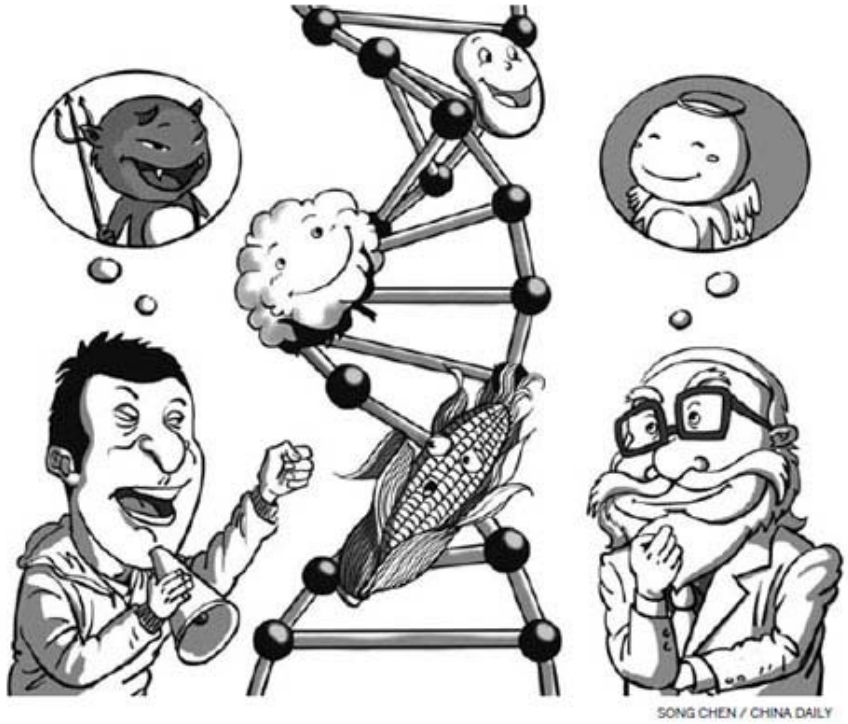
Dealing with wicked problems:

- Authoritative
- Competitive
- **Collaborative**



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SOME CONCLUSIONS

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- It is important to understand the **conceptions** of the genome held by citizens and their **core values**
  - Societal values and principles should govern this technology and not the other way around

- Many citizens feel **vulnerable** when faced with ELSI in genomics
  - Uncertainty, lack of control and comprehension,
  - → Fostering **trust** is key in developing an ELSI framework for genomics

- This trust is best maintained by applying a soft version of the **precautionary principle** to genomics:
  - A narrow focus on informed consent is not enough: citizens demand an elaborate ELSI framework that promotes scientific progress and protects them from harm

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PRIVATE PUBLIC PARTNERSHIP IN ONCOLOGY

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

oncNGS PCP

- **Scope:** Aim to develop integrated solution for testing, analysing, reporting and storage of Next-Generation-Sequencing medical data within routine healthcare diagnostics
- **Budget:** € 12 221 843,75 (90% EC contribution)
- **Reference:** https://cordis.europa.eu/project/id/874467
- **oncNGS website:** http://oncngs.eu/

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

oncNGS challenge

- The challenge will consist in providing:

(1) **efficient molecular DNA/RNA profiling of tumour-derived material in liquid biopsies** by means of
(2) **pan-cancer tumour marker** analysis kit including **NGS analysis** integrated with
(3) an **ICT decision support** system including **test interpretation and reporting**.

✓ Proposal: **Be, Fr, It, Sp, Ger**

✓ Proposal: **about 40 hospitals and PH institutes**

Start date: **01 January 2020** (5y project)

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

Deployment of oncNGS

What we could/should/want to do?

- Develop **common guidelines** on implementing the oncNGS solution in oncology practice (ISO-standardization, harmonization, formalization,….)
- Develop common protocols for **data-sharing**
- Launch **cross-border purchase** procedures
- Develop tools for interactive e-Consults (**molecular tumor boards**)
- Organize joint cross-country **multi-centric clinical trials** applying oncNGS device(s)
- Develop **patient-matching tool** applying oncNGS data (s) ……

EUROPE BEATING CANCER

RTD-driven Target(s)

Core MS HCS activities: NCPs, ECAS, Screening programs, EC Guidelines, …

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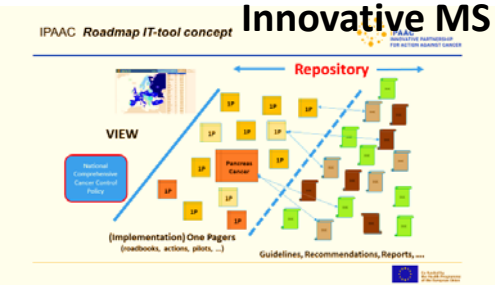
Innovative MS actions



European Commission

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- *Chloé Majeur*
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- *Kris Vranken*
- *Marijke Pauwels*
- *Johan Van Bussel*
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Cancer Register

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- *Nancy Van Damme*

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RELEVANT WEBSITES

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- https://www.compermed.be/
- https://www.wiv-isp.be/QML/
- https://healthdata.sciensano.be/
- https://www.riziv.fgov.be/nl/professionals/verzorgingsinstellingen/laboratoria/Paginas/oncologie-terugbetaling-moleculair-biologische-ngs.aspx
- http://kankerregister.org/
- https://www.ema.europa.eu/en/medicines/human/EPAR/lynparza#authorisation-details-section
- https://ec.europa.eu/digital-single-market/en/public-procurement-innovative-solutions
- https://www.ipaac.eu/
- https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme/mission-area-cancer_en
- https://ec.europa.eu/health/non_communicable_diseases/events/ev_20200204_en

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Thanks

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