

Access to innovative and advanced therapy medicines how to asses, how to pay, how to finance

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Access Time

Italy: average value of 418 days (10th place).

Germany: 120 days

Swi: 166 days

Dan: 169 days.

Ned: 213 days.

Swe: 262 days.

Austria: 302 days.

UK: 335 days.

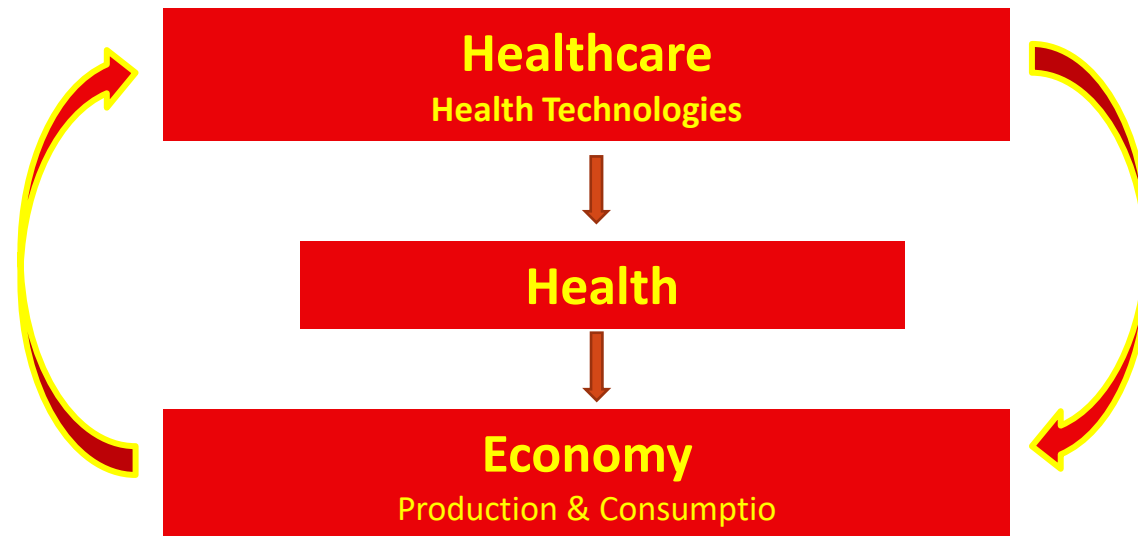
Russia : 384 days.

Macedonia:397 days.

P Russo, FS Mennini, P. Siviero, G. Rasi,
*Time to market and patient access to new
oncology products in Italy: a multistep pathway
from European context to Regional healthcare
providers,*
Annals of Oncology, Annals of Oncology,
2010,10.1093/annonc/mdq097. (2010).

Healthcare Model: Health and Well-being

Health is important for the well-being of individuals and society, but a healthy population is also a prerequisite for productivity and economic prosperity



Covid 19 and Vaccination strategy

Table 5 Summary of economic impact: the enormity of potential GDP losses indicates that the national vaccination plan against COVID-19 represents the single most significant risk for the recovery of the Italian economy

Scenario impact	2021	Absolute value		2022 FCST	Absolute value		2021–2022 Impact	Absolute value	
	Forecast (FCST) €billion	change vs base case €bill	% Change vs base case		change vs base case €bill	% Change vs Base case		change vs BASE case €bill	% Change vs base case
Base case	1,620.6			1,678.9			3,299.5		
Worst case vaccination delay	1,524.4	-96.2	-5.9	1,574.8	-104.1	-6.2	3,099.2	-200.3	-6.1
Worst case delay plus new outbreak	1,489.3	-131.3	-8.10	1,538.6	-140.3	-8.36	3,027.8	-271.7	-8.2
Best case	1,625.3	4.7	0.29	1,683.8	4.9	0.29	3,309.0	9.5	0.3

The stakes are very high both from a social point of view (number of deaths and flooding of hospitals) and from a strictly economic perspective (impact on GDP). If the vaccination were to see its completion only at the end of 2021 (the so-called “the worst scenario”), estimating a quarter of delay due to the availability of vaccine doses, the overall loss in two years (2021 and 2022) would even reach 270 billion (130 billion in 2021 and 140 billion in 2022).

A scenario in which only between the third and fourth quarter of 2021 (therefore between October and December) the vaccination of 75% of the population will be completed will result in losses of up to 96 billion in 2021 and 104 in 2022 (200 billion overall in the two years).

A best (optimal) scenario, which the government also hopes, in which optimal coverage can be achieved (between 62% and 75%) between the second and third quarter of 2021 (therefore by September), would make it possible to cancel the estimated losses in the other two scenarios. Not only that, in this case, a mini growth is estimated equal to 4.7 billion in 2021 and another 4.9 billion in 2022.

Mennini FS, Magni D, Daniele L, Favato G. Knowledge management in turbulent times: time-based scenario analysis of vaccinations against COVID-19. Journal of Knowledge Management, 2021).



Problem

Identifying new strategies for early and appropriate access/intervention can make a difference to people's health and associated costs (both direct and indirect).



Innovation Sustainability and *Governance*

An essential element in the construction of a 'mutually sustainable' system is to **ensure**, as far as possible, **a certain and stable planning and financial framework and also.....**

.....Use Adequate Instruments



What, if anything, has changed with COVID19?

**The need to evaluate, as a priority,
Public Health Interventions**

ATMP?



ATMP

1. They can restore, correct or modify impaired physiological or pathological functions in humans, even by correcting genetically acquired mutations.
2. They have high short-term costs and long-term benefits.





- Economic savings in the perspective of society (direct and indirect)
- Value of the investment
- Recovery of life years lost or life years lived in disability (DALYs)



ATMP

Costs: concentrated in the short term.
.....emerges financial need for expenditure
and the need for budgetary coverage.

Benefits: long term.

.....**investment expenditure**



Traditional reimbursement and budgeting schemes' are not able to write off the value of ATMP.

Split payment?

...pharmaceutical expenditure accounted for in current expenditure!

 Expenditure must be accounted for as investment expenditure

..... paradigm shift in the accounting of certain healthcare costs!



ATMP as investment

Sars-CoV-2 pandemic 'comes to our aid': the **health of EU citizens** and countries is crucial and crucial for **economic and social sustainability and financial sustainability**

Trade-off between health and economy: in reality this is not the case at all, without good health conditions, there are high economic damage, without re-establishing acceptable health conditions, economies will not start again (Healthcare Model)

After Sars-CoV-2, the **Value** of human life and **good health** for **growth potential is evident:** vaccines solve, more or less permanently, epidemic; in the same way, ATMP permanently treats different pathologies

Flow of benefits (direct and indirect) for many years (including effect on productivity) and **cost savings** (lower consumption of drugs and facilities, lower costs for care and family, etc.)

Can we deny the element of investment and **enrichment of the physical, human and technological capital stock** of a nation that derives from ATMP? NO, **but then how can they be economically/accounted for?**



Are ATMP investments under an economic point of view?

- **Net investments** are crucial for the growth of national income and the sustainability of debt
- Recent economic and technological developments have shown that there is a need for a **rethink of the concept of capital, both from an economic point of view, from the statistical point of view and from the point of view of national accounts.**
- In the traditional accounting approach, the **notion of capital usually refers to economic capital**, while it is clear that **human, social and natural capital** (linked to the environment and health conditions) is increasingly important for the future of countries.
- In order to do this, decisive **statistical and accounting innovation** is needed: expenditure on traditional and canonical investments must also be combined with other types of expenditure which current procedures and criteria **consider to be essentially current**:
 - to stay in the health case, how much of the expenses considered current today (for doctors, healthcare equipment, or atmps) actually have an **investment nature**?
 - Without them, even the "physical" part of investment in health care (e.g. a hospital or treatment centre) would not in fact be usable?



"High road" to qualify ATMP as investment expenditure

Why?

The time has come to **review and update the current accounting conventions in a profound way**, considering that **some of the current expenditure is necessary to increase a nation's capital stock and economic assets** – they are therefore decisive for the future of a country and its economic sustainability – and that for this reason they can be considered, at least in part, as investment expenditure

The **accounting criteria are the result of a compromise and are an accounting convention**

It can and must **be updated** in the course of technological conditions, the degree of economic and social development and the common feeling of the nations and peoples of the Community.



KEY MESSAGES

ATMPs are **inherently innovative**: they treat diseases for which there are no clinically viable alternatives.

ATMPs are characterised by a high effectiveness linked to their curative or transformative nature: the benefits are always measured in years, in some cases in ... **decades of life gained** (between 1 and 4) and in **lesser disability**

The impact on the annual budget is limited (if we report it to the years in which the benefits are distributed and considering that the indications refer to limited populations), in the long term it is possible to **record savings in the perspective of the NHS**.

They generate savings in "social costs" due to the high number of life years saved, productivity at work recovered, quality of life. The same intervention can be cost effective in a lifetime perspective and not cost effective in a 10-year analysis.

ATMPs, having obvious elements of **an expense with benefits deferred over time, are in fact similar to an investment expense**

The extended distribution of benefits over a longer period of time suggests a more harmonized **distribution of costs in economic and accounting terms and in line with the realization of the benefits**.

ATMP expenses, similar to expenses relating to fixed investments, are subject to the criterion that the impact on net indebtedness is represented by payments made on the basis of the state of progress (SAL) with the same impact on net indebtedness and needs, corresponding to the payments compared to the benefits of the treatment to which the patient is subjected.

That part of health expenditure that presents a clear misalignment between upfront costs and life-time benefits should be requalified as investments under ESA rules.

Pareto - Marshall

Evaluate (also very early on) the conditions under which an **innovation** can find a place in the budgets of public systems, insofar as it is able to ensure the **'value'** that the community (**and not only the payor**) expects and intends to pay.

 **Marshallian efficiency**



NEVER GIVE UP



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THANKS

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