



#VITA Innovative value of ATMPs

#VITA Working Group
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Advanced Therapies: clinical and economic features



They can **restore, correct** or **modify** compromised physiological or pathological functions in humans, including by correcting mutations acquired on a **genetic basis**



They often **target rare diseases** (orphan or ultra-orphan drugs; $n < 10,000$).



Often provide for a **single assumption** (one-shot), and not extended in time



They have significant costs in the **short term** and **benefits** that extend over a long period of time



They have a very **complex valuation process** and the "traditional reimbursement and budget schemes" are not able to amortize the value of ATMPs.

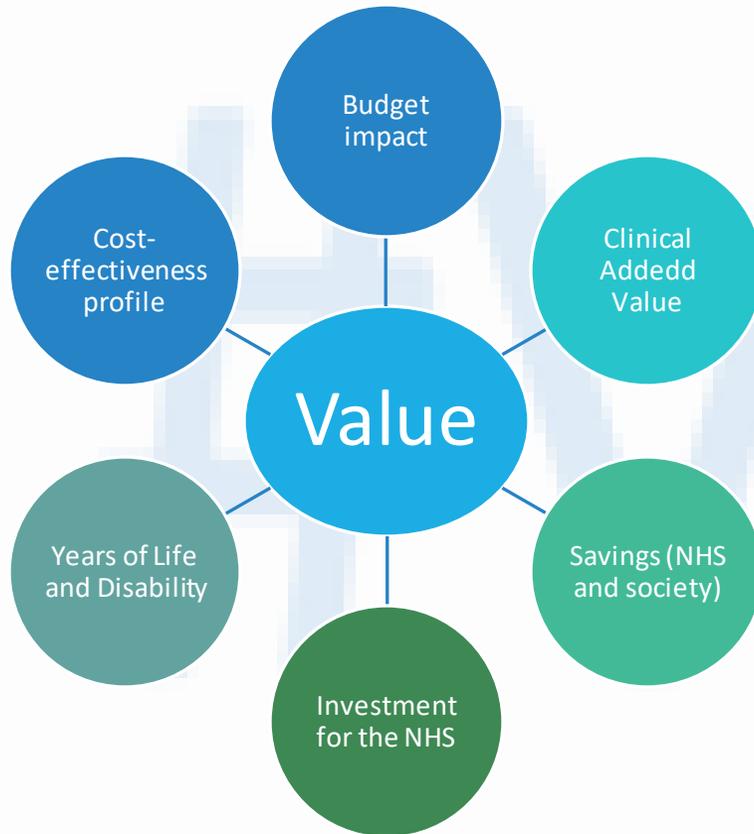


The value framework for ATMPs

- Size of the uncertainty of the clinical effects that must be observed for very long periods of time to determine the real effectiveness
- Multiple dimensions to capture the "value" generated by these therapies especially with regard to economic, social and ethical aspects; Time misalignment between the costs incurred in acquiring the therapies and the related clinical and social benefits, which implies a particular attention to discounting approaches in cost-effectiveness models
- Modalities for the equitable redistribution of economic benefits between the different components of the innovation chain and that of the fruition, hence the need to develop innovative approaches for economic analysis and pricing



The ATMPs value framework



- Long-term budget impact
- Long-term Clinical Benefits
- Economic savings from the perspective of society (direct and indirect)
- Value of the investment
- Recovery of years of life lost, or years of life lived in disability
- Uncertainty in clinical benefits vs. uncertainty in economic impact, and cost-effectiveness profile



The ATMPs value framework

Time asymmetry between costs and benefits



In terms of economic analysis, these therapies present a **high temporal asymmetry** between the **emergence of costs** - which are almost all upfront - and that of **benefits**.

Need **for a different and innovative economic and accounting assessment**



ATMPs **produce direct and indirect benefits over time**



The ATMPs value framework

Frontal costs with long-term benefits



- The decision on which therapy is worthy of funding should be based on an **estimate of the overall economic effects on the health system** and the health of citizens, not only considering the frontal and immediate costs, but also the long-term value to society.
- **The usual economic valuation**, based on the estimation of the cost of traditional therapies (drugs) and on the accrual basis of financial statements, is not very suitable for advanced therapies and their particular technological and industrial characteristics.
- They **require a new health and economic approach**



ATMP as investment 1/2

COVID-19 has highlighted that **healthcare is a fundamental investment** for any country and determines its economic and social sustainability

An increasing and significant proportion **of health expenditure has obvious investment** characteristics (multi-year benefits)

In principle, expenditure on ATMP can be similar to gross fixed capital formation, i.e. the category of acquisitions of movable property, machinery and equipment

But there may also be other possible solutions (production subsidies, intangibles, human capital, R&D, etc.)



ATMP as investment 2/2

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

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?**



Definition of investment

From an **economic point of view**, the **distinction between current and capital expenditure** is essentially based on the assessment of the "different duration of the effect produced by goods and services" obtained from the various expenditures. **Expenditure would be current** if it related to the purchase of goods and services whose "economic usefulness is exhausted in the accounting year in which the expenditure took place"; they would be on the **capital account** when it 'exceeds the year and affects several years'

In **national accounts**, **investment**, i.e. the purchase of tangible or intangible assets (tangible and intangible) and the formation of stocks is known as **gross capital formation** (GCF). When excluding stockpiles (or "changes in inventories"), leaving only **purchases of tangible or intangible goods**, the result is known as **fixed gross investments** (fixed capital formation GFCF).

This aggregate measures total expenditure on 'products intended for use in future production'. They are therefore 'products that can be **reused several times in production processes**'. These types of products are collectively known as **"fixed" capital**.



Definition of fix gross investments

Istat definition. Gross fixed capital formation consists of acquisitions (net of disposals) of fixed capital by resident producers, plus increases in the value of non-produced goods (e.g. land). Fixed capital consists of tangible and intangible assets (e.g. software) produced for use in production processes for a period of more than one year.

Definition SNA 2008. Fixed assets are produced assets that are used repeatedly or continuously in production processes for more than one year.

Definition Lequiller, Blades, 2014. Gross capital stock is the value of all fixed assets still in use, at the actual or estimated current purchasers' prices for new assets of the same type, regardless of the age of the assets. Net capital stock is the sum of the written-down values of all the fixed assets still in use; it can also be described as the difference between gross capital stock and consumption of fixed capital.



Definition of intangible fixed asset

- **OECD definition.** Intangible fixed assets are non-financial produced fixed assets that mainly consist of mineral exploration, computer software, entertainment, literary or artistic originals intended to be used for more than one year.
- **DEFINITION ONS, UK.** Intangible fixed assets include mineral exploration, computer software and entertainment, and literary and artistic originals. Expenditure on them is part of gross fixed capital formation. They exclude non-produced intangible assets such as patented entities, leases, transferable contracts and purchased goodwill, expenditure on which it would be intermediate consumption.
- **IPSAS31 definition.** An important contribution to the definition of intangible assets is that of the International Public Sector Accounting Standard Board (IPSASB) of the International Financial Reporting Standards (IFRS) Foundation.



Assessment of the perimeter of investments can be considered as some firm points

The definitions and conventions used in the national accounts are international: it must be possible to compare national accounts data between countries.

The international community periodically updates definitions and rules for compiling national accounts as the scientific and political-institutional debate evolves, and the concrete feasibility of applying changes in the accountancy system.

In the debate and updating process, the alignment between the system of national accounts and that of commercial activities (links to commercial accounting, 2008 SNA, p.433) is important. The International Accounting Standards Board (IASB) has become increasingly important as a subject setting standards for commercial accounting. The IASB promulgates the International Financial Reporting Standards (IFRS).

The updates of the Regulations are long processes, they pass through working groups, they can provide for intermediate phases with satellite accounts and experiments. They certainly need a political boost from the Council and/or the European/Local Parliament.



Are ATMP investments under an economic point of view? 1/2

- In terms of economic analysis, ATMP therapies have very special characteristics:
- they have a **high temporal asymmetry** between the emergence of costs – which are almost all upfront – and that of benefits. This is perhaps the main aspect that suggests an economic and accounting evaluation of these different and innovative therapies
- **produce direct and indirect benefits over time:**
 - In terms of savings: **healthcare savings**, **drug consumption** and **health services** of different kinds; the reduction of resources consumed directly in health centres and the reduction of family and **direct and indirect care resources**
 - In terms of value: the increase in life expectancy, the improvement of the qualities of human life, the treatment and stabilisation of different pathologies (with a clear impact **on the value of human life**); but also in terms of increasing the state of health of patients; **increased productivity**, **higher tax revenues**; the possibility, after the remission of the disease, to be able to continue to educate and participate in collective life; the **lengthening of the potential pension burdens**



Are ATMP investments under an economic point of view? 2/2

- **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?



Do ATMP have the characteristics of investment for accounting purposes? 1/5

The key questions are:

1. Are ATMP tangible or intangible assets?

"An intangible asset is by definition an asset without physical substance.... They cannot be held in the hand, or tagged with an inventory system" (EPSAS, 2018). More precisely, "an intangible asset is an identifiable non-monetary asset without physical substance" (IPSAS 31). ATMP is a genetic material, but also 'algorithms', personalized and 'transfection' to people suffering from specific pathologies. Are they tangible or intangible goods?

Surely they are goods produced thanks to scientific research with the aim of healing pathologies and therefore with lasting effects on clients, people's well-being, production potential and health costs.

But regardless of how ATMP is classified as goods, the following two requirements must be met for recognition among gross fixed capital formation.



Do ATMP have the characteristics of investment for accounting purposes? 2/5

Are ATMP the product of a production processes?

Yes, they are products of complex production processes, characterized by a relevant research component. The first requirement to be able to consider ATMs as capital goods is met

Are ATMP used multiple times or continuously within the same processes for more than a year?

The production process takes place in a first phase in the laboratory, and in a second phase within the organism, continuously over time, and with personalized characteristics with respect to the person. The second requirement to be able to consider ATMP capital goods could be considered fulfilled. In fact, a distinctive aspect of ATMP, compared to traditional drugs is that, after 'transfection' in the body, the next stage of the production process is internal to the organism and is continuous over time.

It is this characteristic that allows ATMP to maintain their healing action resulting in a permanent or prolonged improvement over time in the state of health and therefore in the affective and working life of people. As a bridge improves mobility between territories and can be used over time, scientific research increases knowledge wealth and allows further progress, defense system spending improves citizens' security for an extended period, ATMP improves living conditions, generates significant direct and indirect savings for the NHS and people's productive potential , if not permanently, definitely for an extended period of time.



Do ATMP have the characteristics of investment for accounting purposes? 3/5

2. If ATMP are classifiable as intangible assets, would the other requirements set out in ISAS 31 be met?

- **Identifiable.** Is the asset identifiable, i.e. is it separable (i.e. can it be sold, transferred, leased, licensed or traded) or does it derive from legal or contractual rights? Identification does not necessarily imply transfer but may result from contracts or legal rights. In the case of ATMP, identification derives from contractual rights. In fact, the NHS when it buys an ATMP would sign a purchase contract conditional on its effectiveness. The NHS pays the installment if the drug works, so property rights on that drug only transfer to the NHS if the effects of the drug are lasting over time. The NHS buys only the durable part of the drug and not all the drug.
- **An entity's control of the asset.** The NHS currently has control over the acquisition of ATMP, i.e. it has the power to obtain future economic benefits or service potential from the underlying business and to restrict others' access to such benefits or potential service
- **Potential future economic benefits and service.** Future potential economic benefits or service are likely to flow to the entity. The requirement is met, vis-à-vis the NHS
- **The value of benefits can be reliably estimated.** This requirement is also met as the benefits can be identified and quantified and the cost value of ATMP can be reliably assessed



Do ATMP have the characteristics of investment for accounting purposes? 4/5

Conclusions.

On the basis of the above considerations, there appear to be sufficient evidence to be able to understand ATMP as an intangible component of gross fixed benefits.

On the other hand, the perimeter of intangible assets is a subject under study and discussion at international level among national accountants. At European level, several informal working groups are being promoted by the Commission and Eurostat to assess intangible expenditure, environmental expenditure, accounting treatment of social benefits



Do ATMP have the characteristics of investment for accounting purposes? 5/5

What is the value of ATMP that could be accounted for? The cost-side approach or the expected net economic value (VANE)? How can it be accounted for over time in line with the time distribution of their effects?

As evidence of the consideration of future economic benefits as an estimate of the increase in the value of the capital stock from intangible assets, in the ESA Regulation 2010, it is stated that the

"value of expenditure on creative work undertaken on a systematic basis in order to increase the wealth of knowledge, including knowledge of man ... is determined in terms of the expected economic benefits in the future. Unless reasonably estimated, the value shall be calculated, by convention, as the sum of the costs, including those of research and development which has not produced results. Research and development that does not provide benefits to the owner is not classified as an activity, but is recorded as intermediate consumption (AN1171)"

The estimation of the net economic benefits deriving from ATMP will therefore benefit from the extensive literature on methodologies for estimating the effects of investments in health on the well-being of the population and on the income produced. In #VITA, the company has developed a Budget Impact Life Time model that allows the payer to make such an estimate



Revisions of national accounts: recent experience

In the 1993 SNA, the scope of investment was expanded to include **software, mining exploration, artistic originals, and valuables expenses**

In the **SNA 2008**, the scope of investment was **expanded to include R&D and military defense spending**

The **2010 ESA** expressly acknowledges that: "research and development expenditure" and "**military expenditure**" are **investment in nature**, so they are recorded as gross fixed capital formation and no longer as current expenditure. The identification and treatment of R&D as an investment is based on the "value in terms of future economic benefits" (pg 216 of the SEC 2010). Similarly, expenditure on military systems is also investment in nature. The new accounting system realistically recognises their productive potential for a country's external security over several years.

In the Italian context, a crucial point is the criterion established in the **Manual on Public Deficit and Debt** (for R&D and the armaments sector) since the same logic adopted for the public good of security should apply to the **public good of health**. It would be very embarrassing for the public budgetary authorities to declare that they were not prepared to follow this line, after the funds for the epidemic



"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 MESSAGE

- 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 requalifies as investments under ESA rules





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