



# Progetto #VITA Add-On al TARS

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Touch Points– 10/3/2021

## ATMP as investment 1/2

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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.)



**Italian Public accounting rules (RGS, 2019): Investment expenses** identify all expenditures that **directly or indirectly affect the formation of national, physical and human capital**. In the current definition, public investment is represented by the "*volume of expenditure that the State, the regions, and other public administrations bear with the aim of increasing the stock of physical and technological capital available to the country*".



## ATMP as investment 2/2

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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

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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

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**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

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- **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

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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

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- 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

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- **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

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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 clinics, 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

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

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### 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

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**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

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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 1/2

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### 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.



## "High road" to qualify ATMP as investment expenses 2/2

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### What?

- **Political will on the part of the Italian Government** to qualify ATMP as investment expenses from an accounting as well as an economic point of view; crucial role groups/Commissions Parliament
- **Ok of Istat** (which must still confront Eurostat) and therefore of the State Accounting Office to follow this criterion
- **Political will on the part of the European Council**, which can be activated by the European Parliament and the Commission (role of various Working Groups Eurostat and Stat/Dir UE)
- **SEC 2010 update** with requalification of ATMP as investment expenses (already scheduled to complete upgrade by 2025)



## ..... and in the interim how to implement multi-year payment models?

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- **Demonstrate to the public decision-makers that ATMP** can be classified as investment expenditure as it has already done with military spending and research and development expenses, certainly at an economic level
- Demonstrate the **ability to measure the benefits over time** and the savings generated for the NHS through a Lifetime BIM model
- Apply the conventional criterion applied for gross fixed investments according to which the impact on net debt is represented by payments made **on the basis of work progress (SAL) and can also be extended to expenses for ATMP** with the same impact on net debt, corresponding to **payments related to the benefits of the therapy to which the patient is subjected**
- **Implementation of agreements transposed by administrative or regulatory acts**, between the public payer and the producers of advanced therapies, so that **legal competence follows economic competence, through the construction of an ad hoc standard containing a specific authorization of expenditure of a multiannual nature**

In this way, the **time-based scan of the public budget expenditure authorisation** could be broadly aligned with that of the effects in terms of therapeutic benefits on patients



# Other solutions to properly finance ATMP? 1/2

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## ▪ Rotary ad hoc fund for ATMP with the following main characteristics:

### ▪ Access criterion (these parameters will be evaluated with the help of **BIM Lifetime**):

- ATMP qualified under the EU Regulation (they will not be linked to innovation to avoid the threshold of 36 months)
- be curative or transformative of the patient's clinical history through a single administration of the
- produce direct and indirect benefits on the system with multi-year effects
- significant organisational impact on welfare processes
- significant implications for patients' quality of life, caregiver and society

### ▪ Payment

- expenses incurred for the purchase by accredited centres for the administration of Advanced Therapies in proportion to the expenditure incurred by them for the purchase of such therapies

### ▪ Financial coverage:

- for the first three years through the allocation of European funding or as an alternative from the Structural Funds
- for the following years the fund will repay the expenses made thanks to the direct and indirect savings generated by atmps that have accessed the fund and measured through BIM Lifetime



## Other solutions to properly finance ATMP? 2/2

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- Implement the installment payment at the level of individual health companies by acting on the 'eligible deficit' by derogation? (to be explored if of interest to companies)
- Study a different funding formula and with third parties:
  - dedicated bond issue and ask for resources on the market (either directly or through Cdp)
  - involve a third market player in the construction of the financing and distribution mechanism for payment and cash flows (Montazerhodjat et al., (2016) proposed that Hedge Funds are well placed to provide loans for high cost therapies)
  - involve institutional investors (pension funds, pension funds, insurance funds, foundations) in the financing of an ad hoc private fund or a dedicated issue by a third party market

