Health technology assessment for academic ATMPs

Three scenarios

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"CREATIC as the flagship in CEE region, provides excellent research of gene and somatic cell therapy to deliver safe, accessible and affordable personalised treatment of life-threatening or chronically debilitating rare disease patients that are conventionally considered incurable."



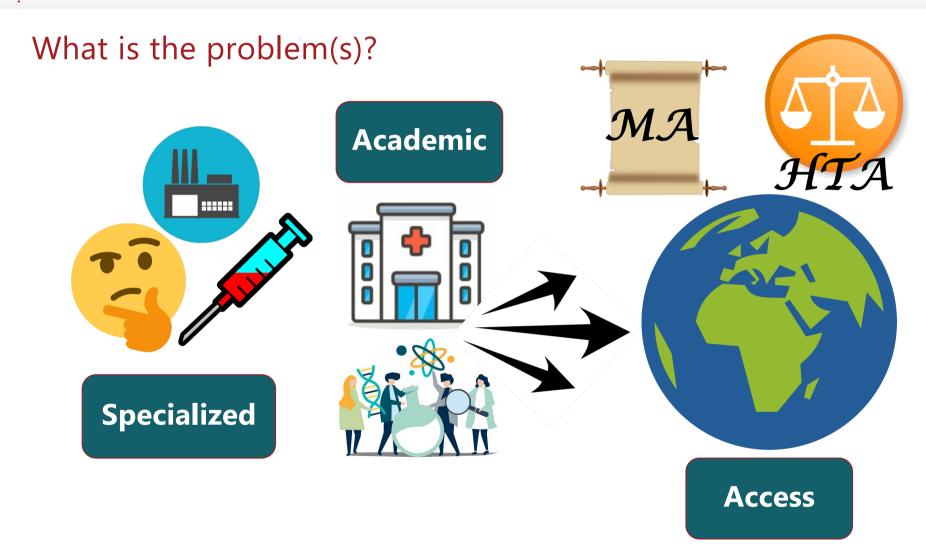












What is the problem(s)?

market Access tied to market Approval



Experience



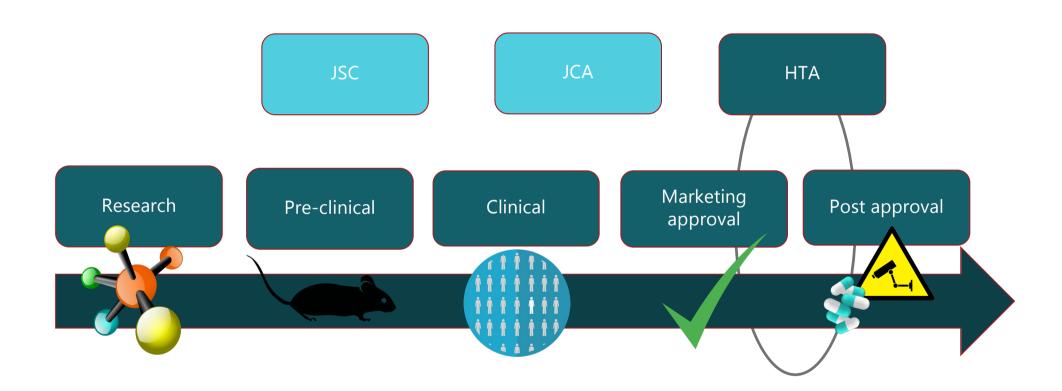
Evidence



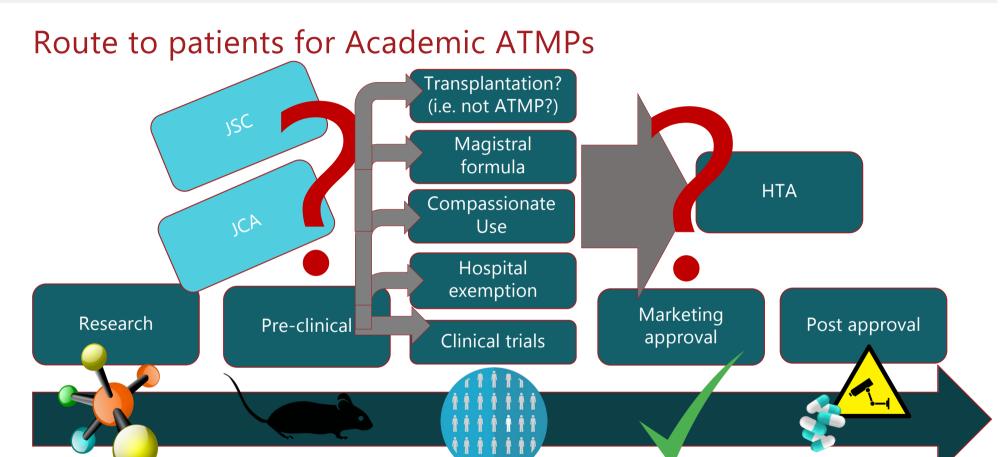
Economy

5

Route to patients "conventional medicinal products"



6



Three routes for Academic ATMP's

Spin-Out

ATMP is sold or licensed to a company that continues its development towards MA

"Classic techtransfer" - feasibility?

Spin-in

Academic institution pursues a Marketing authorization for the **ATMP**

Organisational competences? **Priorities?**





Spin-around

ATMP use by the academic institution continues without a marketing authorization

Duplication of efforts? **Sustainability?** access?

Disconnect MA & HITATUP'S
TO OPEN UP ISCA TO BATTUP'S

EU-HTA

- JCA, JSA/prevent duplication

National-HTA

- is it worth paying for? / healthcare system-fit

National-HTA

- is it worth paying for? / healthcare system-fit

Hospital-HTA

- Hospital / can we deliver? / implementation feasibility

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Hospital-HTA

- Hospital / can we deliver? / implementation feasibility

Integrate Hospital based HTA

To enable treatment tranfer & collaboration