

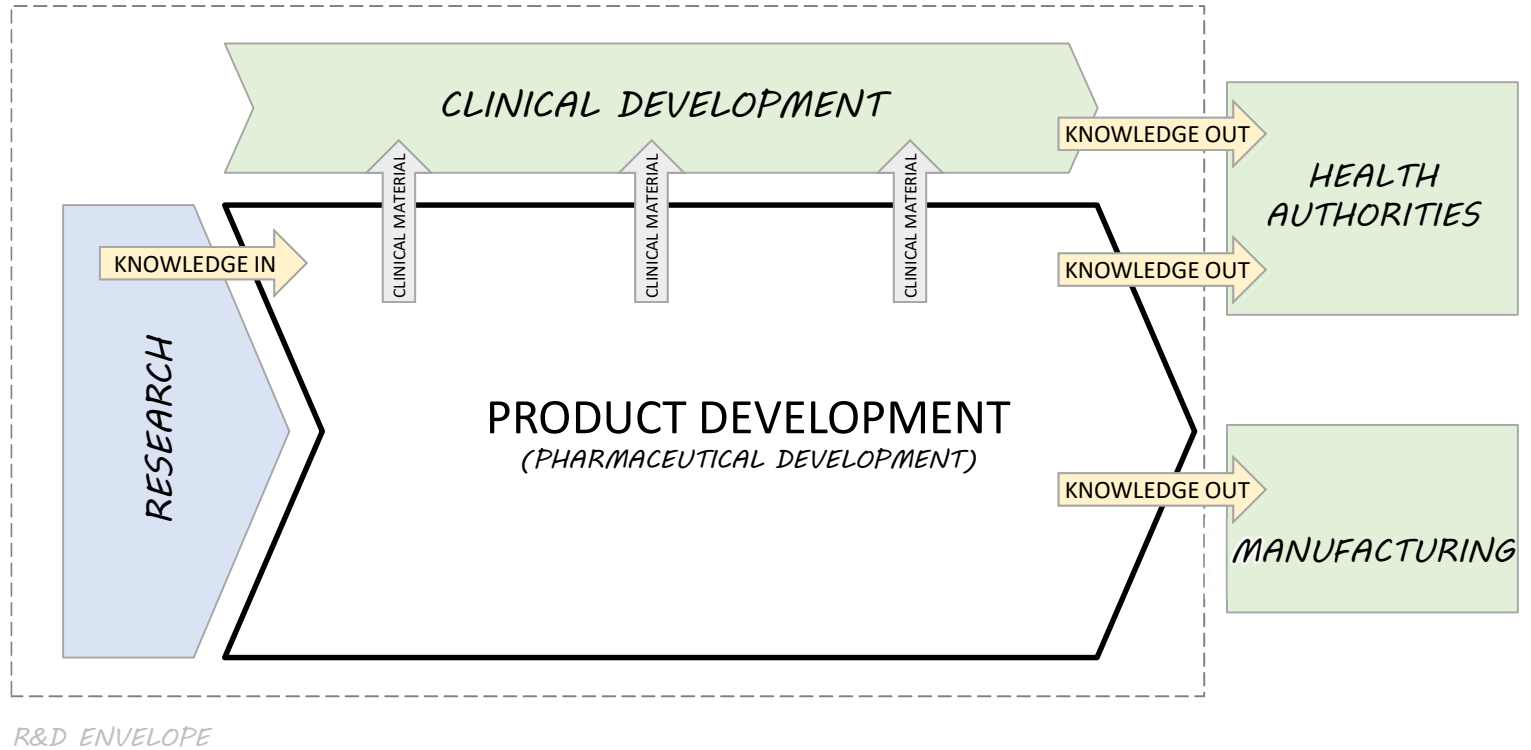
“The pharmaceutical industry manufactures information in capsule form.”

- Peter Drucker (sort of)

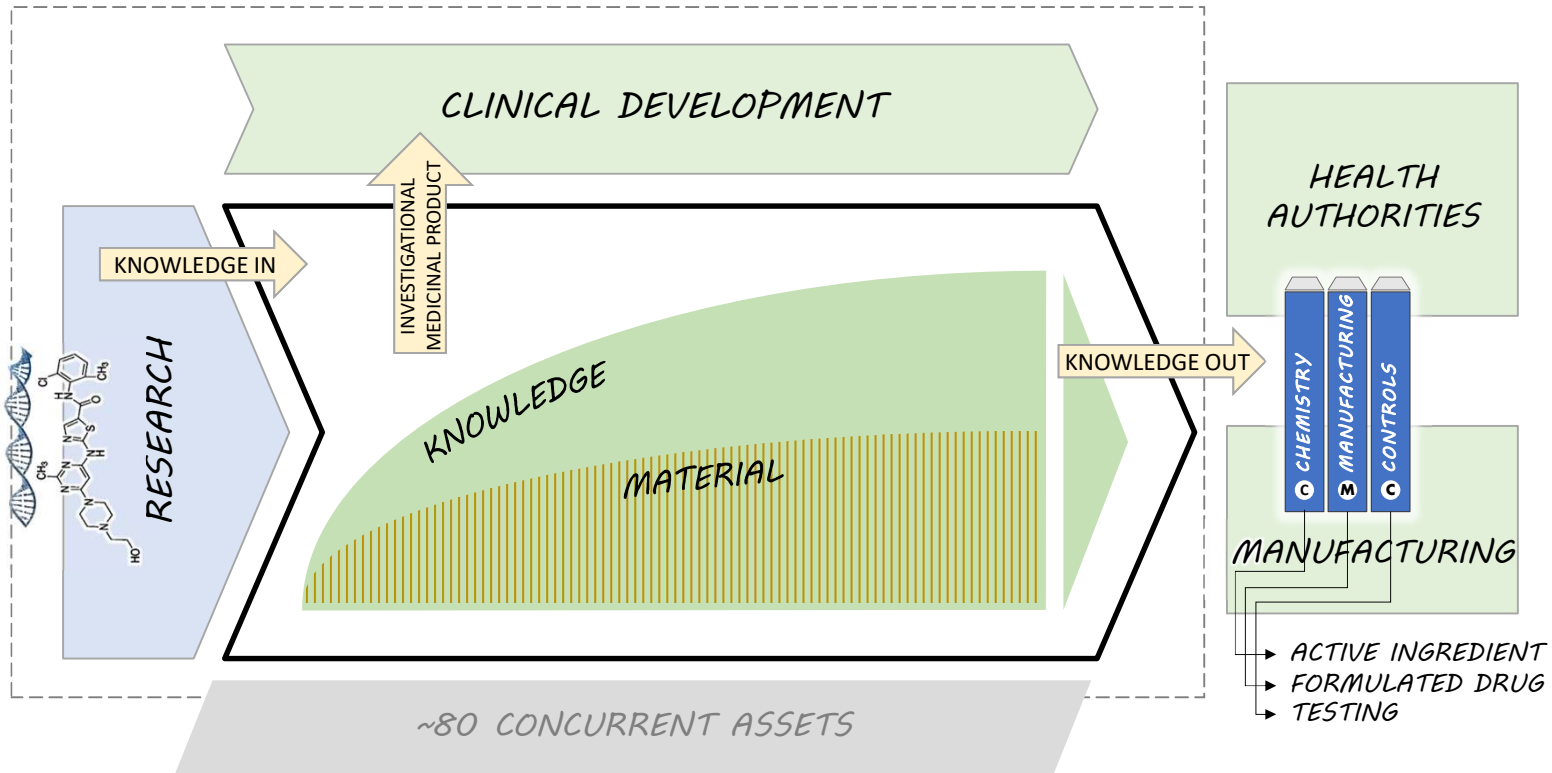
“Product Development manufactures knowledge; Operations manufactures material.” – Akin Davulcu

“Operations does one thing a million times; Product Development does a million things one time.” – Jay Brumfeld

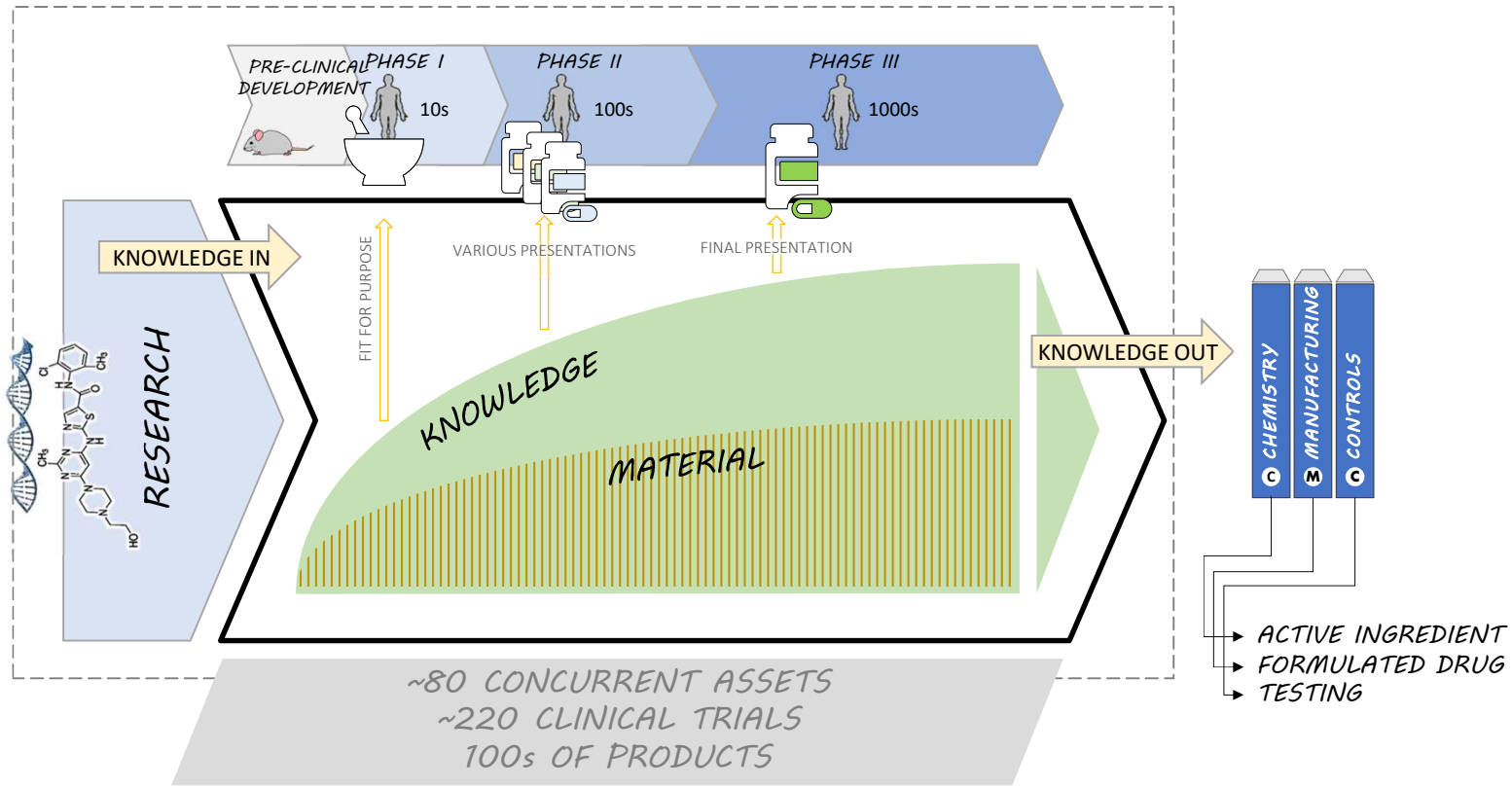
- Health Authorities: FDA, EMEA, etc.
- Research: drug discovery
- Clinical Development: experiments in humans. Split into early development (ED) and full development (GDD)
- R&ED: Research & Early Development
- GDD: Global Drug Development
- GPS: Global Product Development & Supply, operations, supply chain, quality (manufacturing)
- IMP: Investigational Medicinal Product



- **CMC:** Chemistry, Manufacturing & Controls, repository of PD knowledge for each asset
- **Asset:** API + indication
- **API:** active pharmaceutical ingredient, treatment constituent(s) that perturbate disease state
- **Drug Substance:** active ingredient, **API**
- **Drug Product:** active ingredient + everything else to make finished product
- **Controls:** collection of tests that can show manufactured material is within its specifications



- **Excipient:** non-API drug ingredients that make it consumable and control performance
- **Drug Product:** API + excipients + delivery tech + container; API + everything else
- **Formulation:** A unique combination of API + excipients; the recipe for
- **Presentation:** a version of a drug product
- **Pre-clinical:** animal studies required by regulation
- **Phase I:** safety
- **Phase II:** efficacy, dose and formulation
- **Phase III:** statistical confirmation
- **Double Blind Trial:** neither investigators nor patients know who is receiving active or placebo
- **Placebo:** an inactive medication given in place of a medication



- **GMP, Good Manufacturing Practices:** *regulatory guidelines for the control of manufacturing*

- **MAB, Monoclonal Antibodies:** *antibodies with high specificity for an antigen or epitope made with cells all derived from a single clone cell*

- **Analytical Test:** *A measure of a substance attribute, may require multiple methods*

- **Analytical Method:** *technique used on material to determine an attribute*

- **Specifications:** *criteria to which a new DS/DP should conform*

- **PAT, Process Analytical Technology:** *in-line assessment of material attributes in real time.*



PRODUCT DEVELOPMENT (PHARMACEUTICAL DEVELOPMENT)

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- **Modality:** *type or kind of active ingredient*

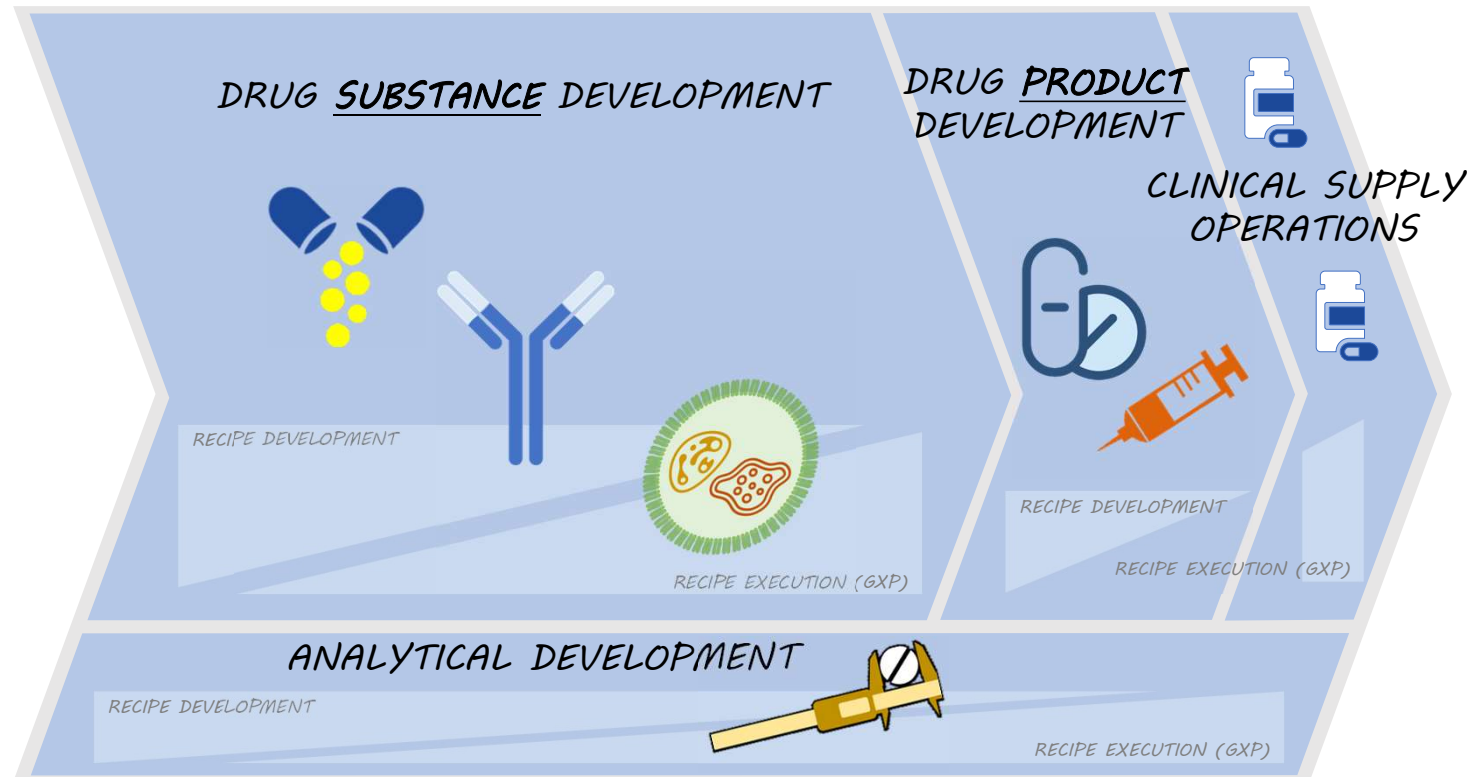
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• **Chemical Process:** clinical route instantiated in large scale equipment

• **Clone:** single cell of a collection of identical cells derived from a single parent

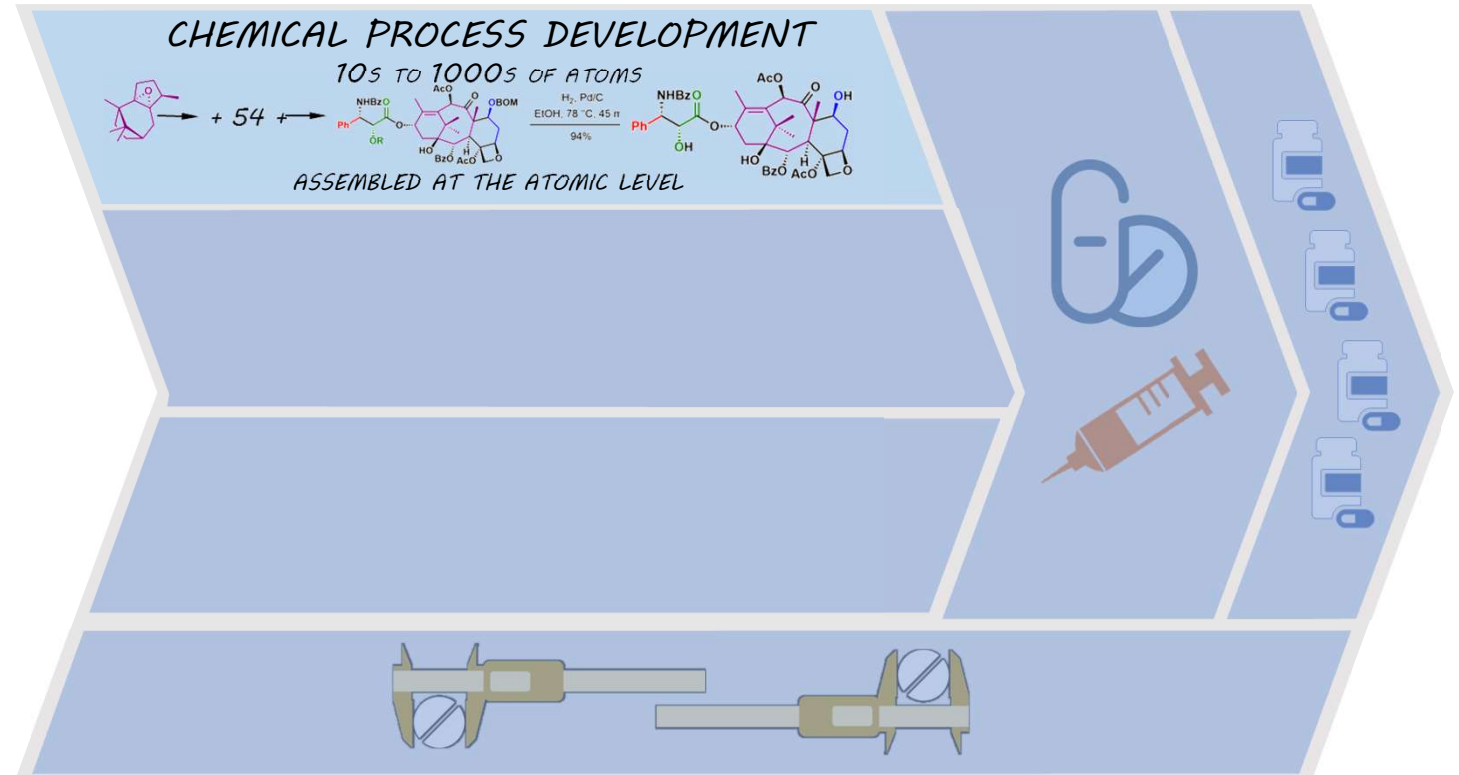
• **Upstream:** biologics clone selection, inoculation, culture

• **Downstream:** biologics harvest, filtration, purification

• **Titer:** the amount of an expressed agent relative to the volume of upstream liquid containing the agent (mass output / bioreactor volume)

• **Leukapheresis:** lab procedure removing blood, separating white blood cells (leukocytes), and returning remainder

• **Car-T:** chimeric antigen receptor, T-lymphocyte



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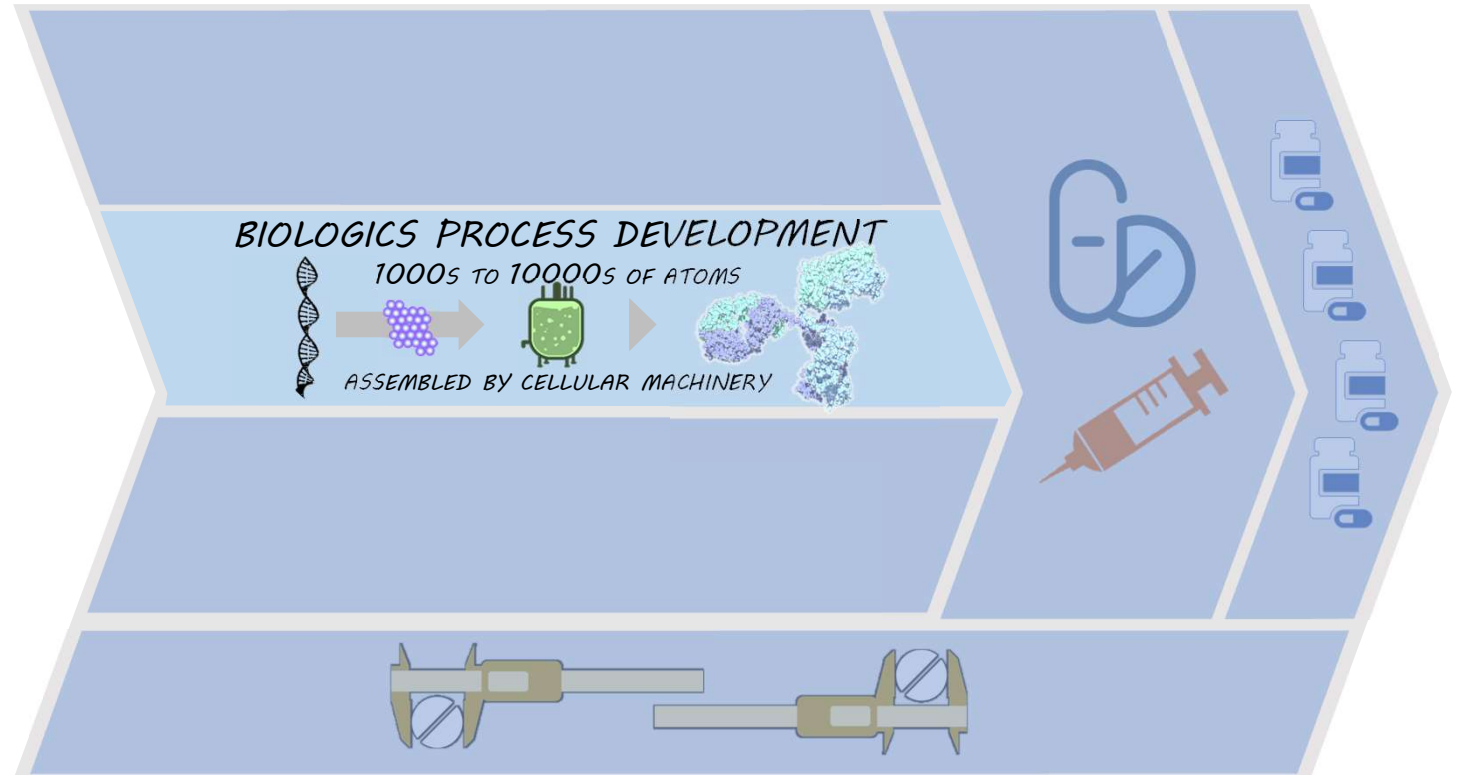
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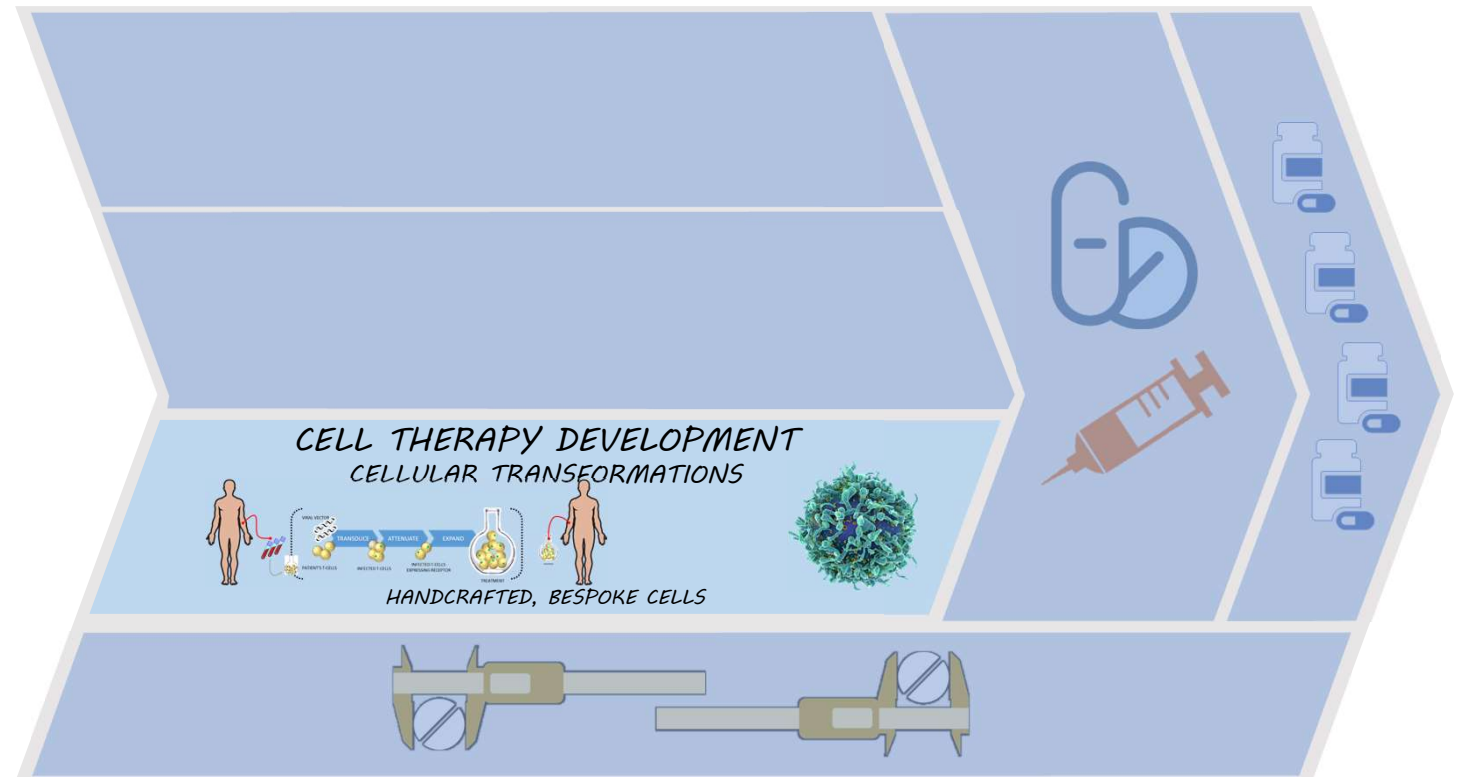
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• **Randomization:** assigning patients by chance to groups that receive different treatments

• **Double Dummy Double Blind Trial:** Using placebo duplicates of the active and comparator because they cannot be made indistinguishable

