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Research on Medicines**

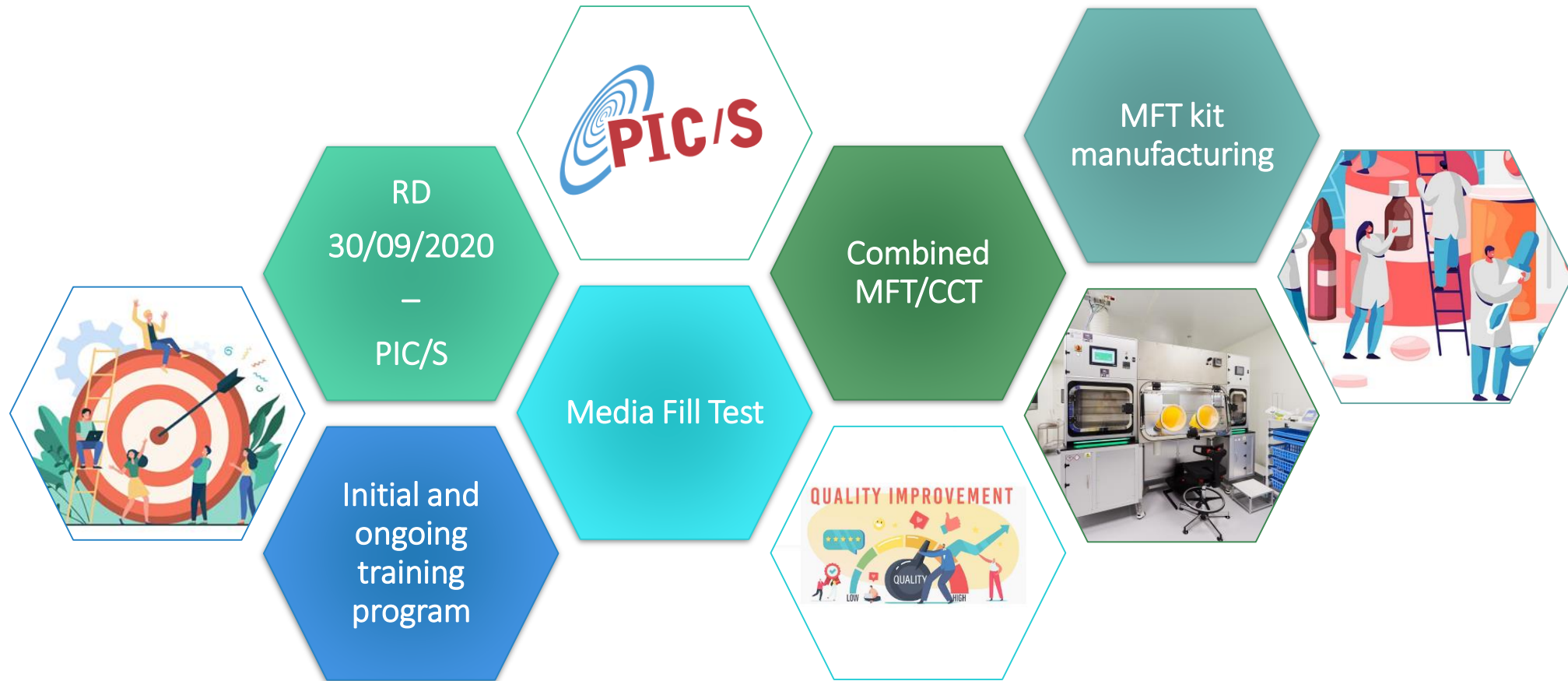
# VALIDATION OF A CUSTOMIZED COMBINED CHEMICAL AND MICROBIOLOGICAL TEST FOR QUALIFICATION OF ASEPTIC PREPARATION PROCESSES

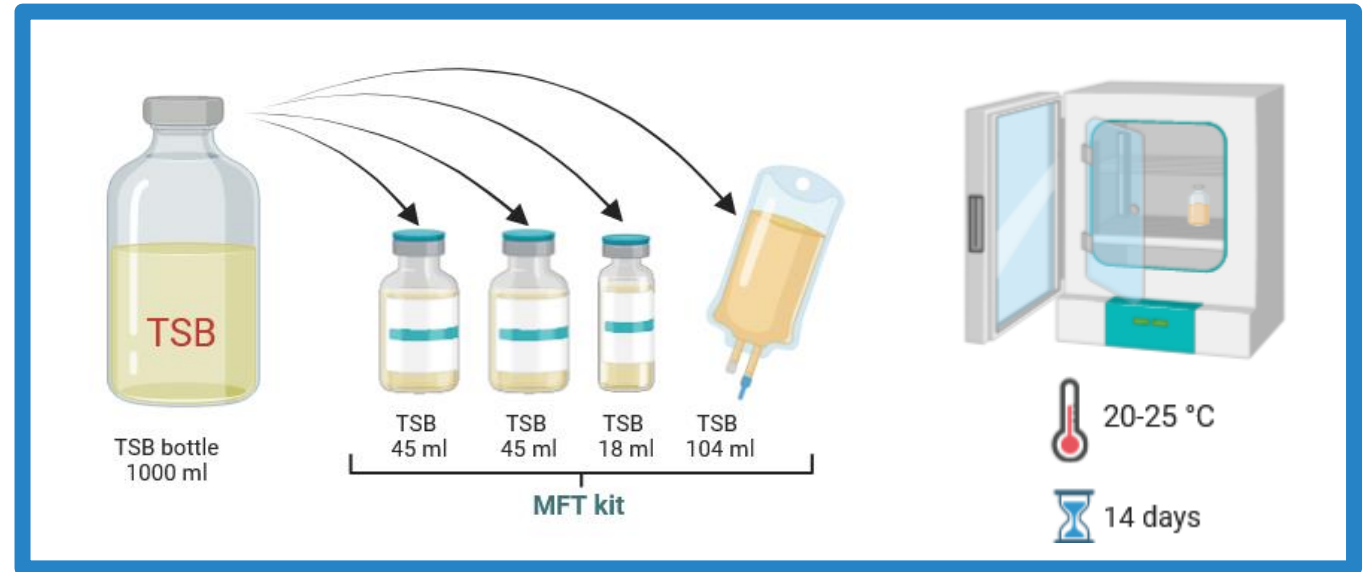
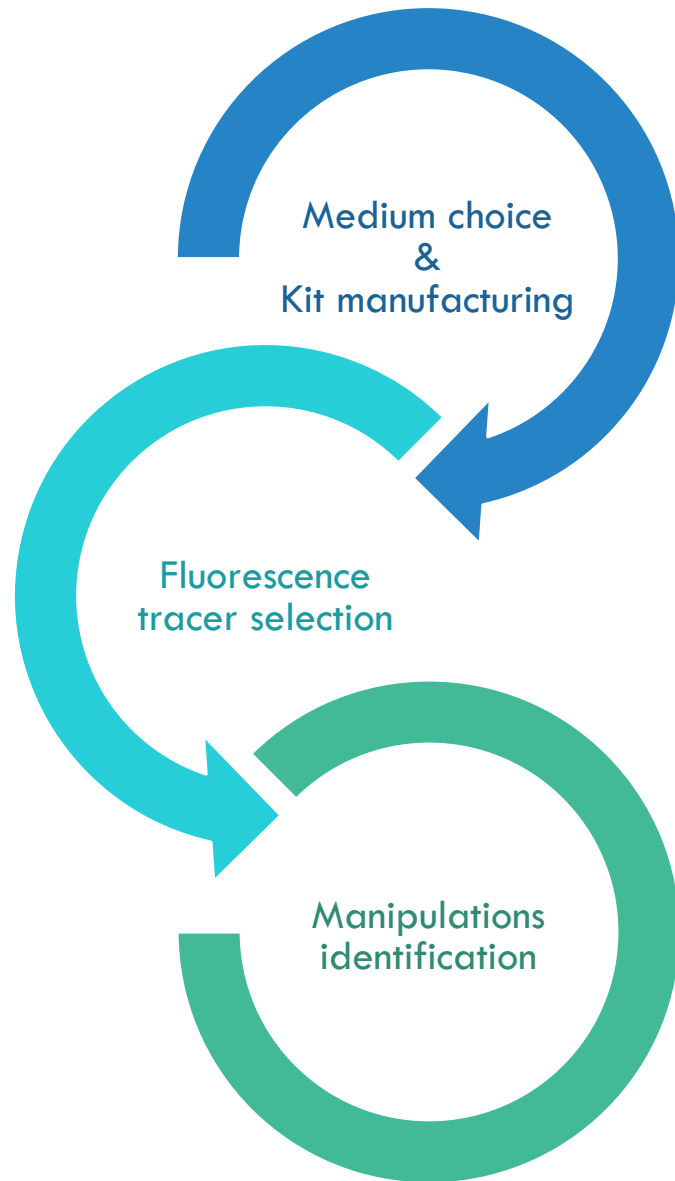
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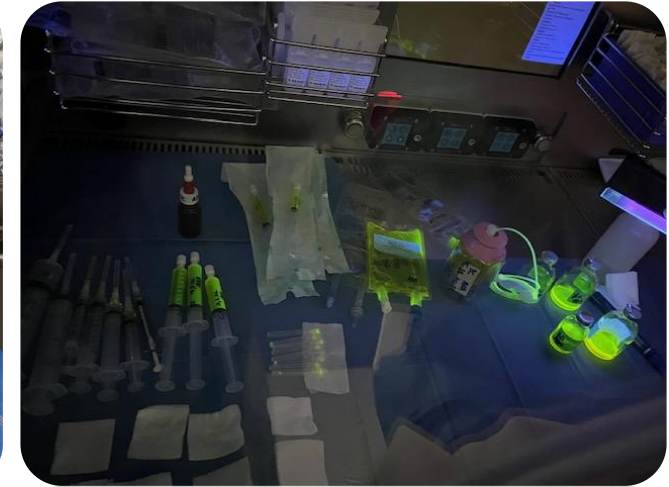




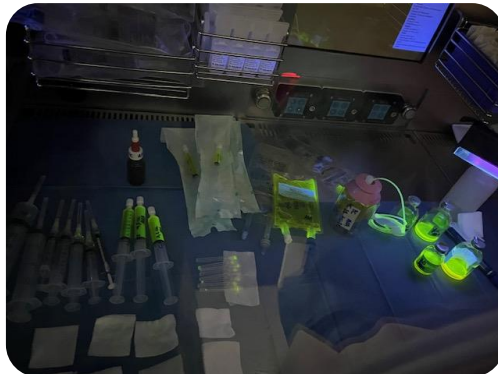
#### List of manipulations

- Aseptic transfer of a solution into a 100 ml bag;
- Aseptic transfer of a solution into a 10 ml eye drop vial;
- Aseptic transfer of a solution in syringes with stopper;
- Aseptic transfer of a solution into a 120 ml elastomeric diffuser.

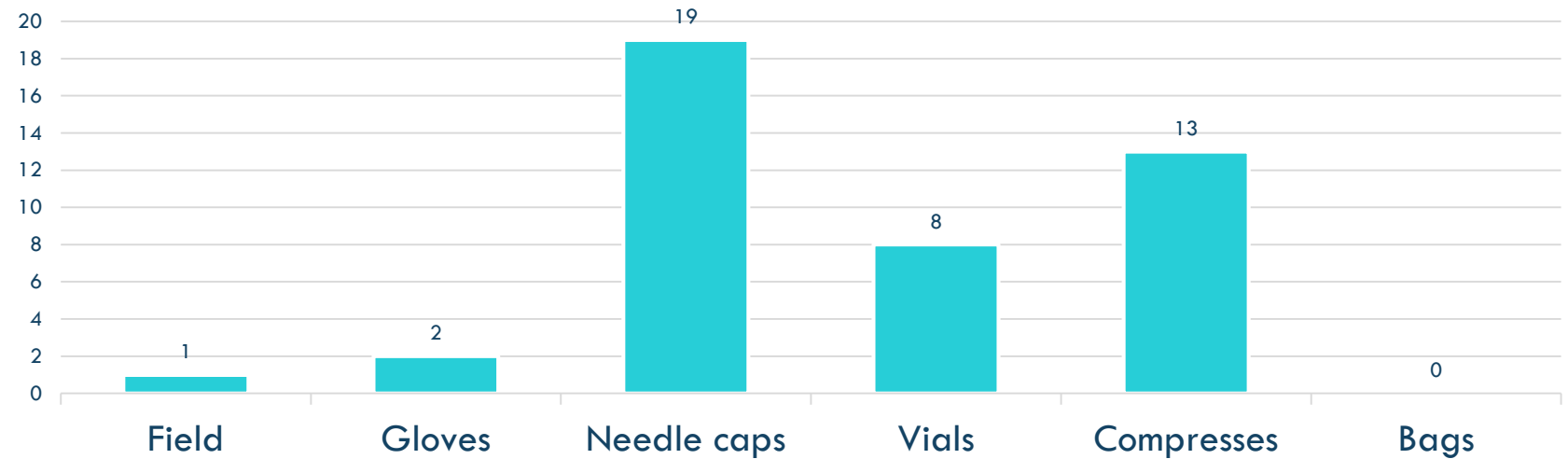
	Fluorescence (λ=366 nm)	Fertility (Ph.Eur. 2.6.1.)
TSB	✓	✓
TSB + acidified quinine 5.0 mg/ml	✓	✗
TSB + fluorescein 0,01%	✓	✓

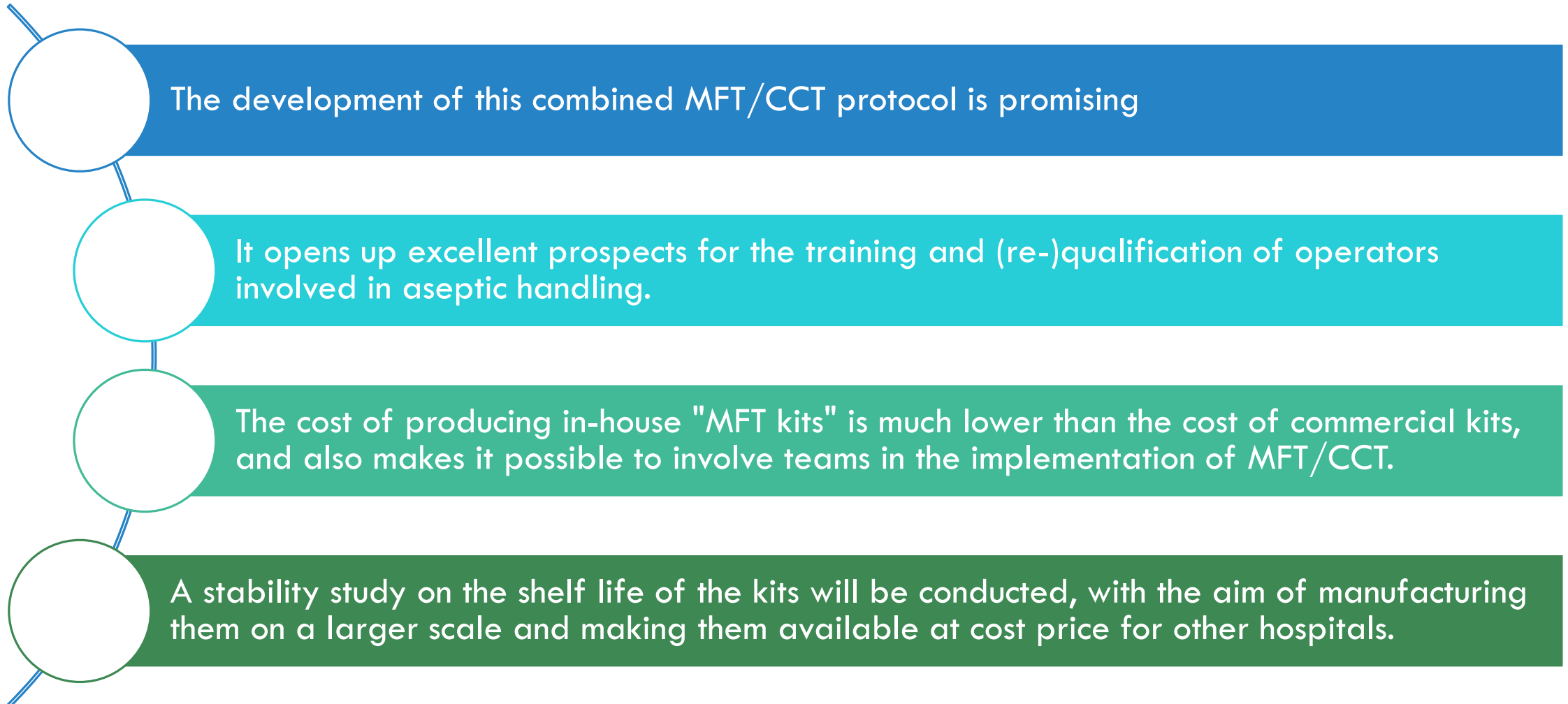


Microorganisme	Milieux	Croissance bactérienne visible à l'œil après inoculation de 13 CFU	Croissance bactérienne visible à l'œil après inoculation de 38 CFU
<i>Staphylococcus aureus</i>	Milieu 1	Négative à 72H	Négative à 72H
	Milieu 2	Positive à 24H	Positive à 24h
<i>Pseudomonas aeruginosa</i>	Milieu 1	Négative à 72H	Négative à 72H
	Milieu 2	Positive à 24h	Positive à 24h
<i>Bacillus subtilis</i>	Milieu 1	Négative à 72H	Négative à 72H
	Milieu 2	Positive à 24h	Positive à 24h
<i>Candida albicans</i>	Milieu 1	Croissance fongique visible à l'œil après inoculation de 24 CFU	Croissance fongique visible à l'œil après inoculation de 77 CFU
	Milieu 2	Positive à 24h	Positive à 24h
<i>Aspergillus niger</i>	Milieu 1	Croissance fongique visible à l'œil après inoculation de 12 CFU	Croissance fongique visible à l'œil après inoculation de 69 CFU
	Milieu 2	Positive à 24h	Positive à 24h



Distribution of areas spotted by the technician during MFT/CCT  
(n=20 technicians - several areas per technician were sometimes observed)







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Keywords:

combined MFT/CCT, fluorescent tracers, microbiological contamination, chemical contamination, operators' validation, sterile compounding.



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