



# Biologics Testing Solutions

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Biologics Solutions

# Premier, Global CRO to Support Biologics Manufacturing



**20%+**  
Robust,  
**double-digit**  
revenue  
growth  
(2020 & 2021E)

**Rapidly  
growing  
market**  
fueled by C&GT  
programs &  
COVID-19  
therapeutics



**A leading**  
CRO in  
**\$1.8B-  
\$2B**  
addressable  
market sector

Synergistic fit with  
**Cognate**  
to establish a  
premier partner for  
testing and  
manufacturing for  
advanced drug  
modalities



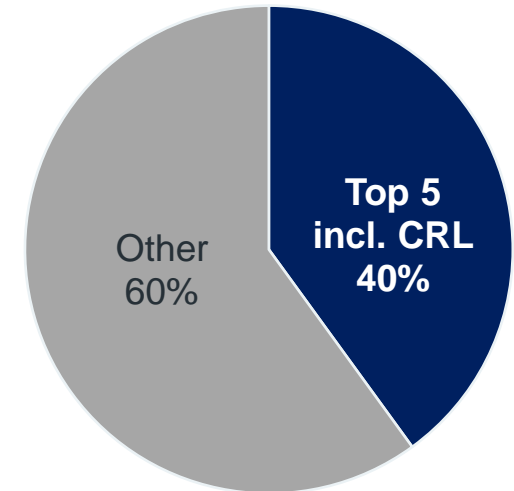
# Manufacturing Solutions

Providing reliable, innovative, scientific solutions to ensure the safety and efficacy of clients' products

Product & Genetic Characterization Services	Biosafety & Clearance Testing	Bio-Activity & Potency Testing	Manufacturing
<ul style="list-style-type: none"><li>• Biophysical testing</li><li>• Analytical testing</li><li>• Genetic testing</li></ul>	<ul style="list-style-type: none"><li>• Viral analysis</li><li>• Microbial analysis</li><li>• HCP analysis</li><li>• Residuals testing</li><li>• Clearance studies</li></ul>	<ul style="list-style-type: none"><li>• <i>in vivo</i> bioassays</li><li>• <i>in vitro</i> bioassays</li><li>• Analytical testing</li></ul>	<ul style="list-style-type: none"><li>• Cell bank manufacturing</li><li>• Viral manufacturing</li></ul>

## Biologics Testing Share\*

\* Excludes C&GT CDMO



Source: CRL management estimates

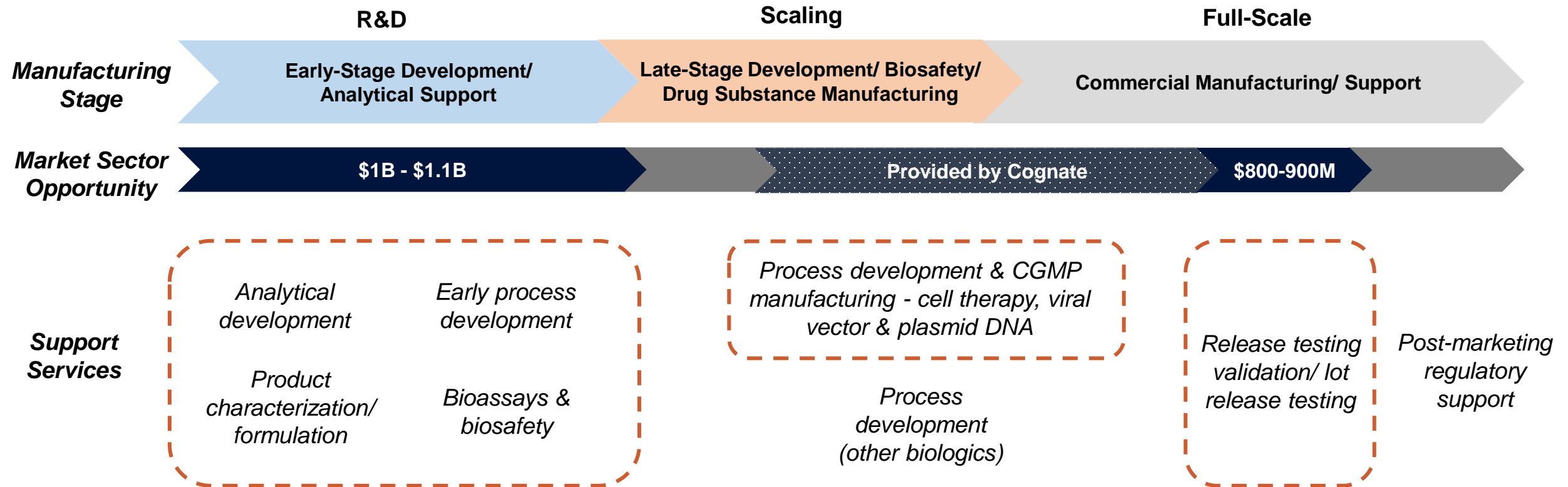
With 50 years of experience, CRL's comprehensive in-house testing portfolio supports over 200 licensed products for biotechnology and pharmaceutical companies worldwide

# Biologics Market Sector Opportunity

Key:

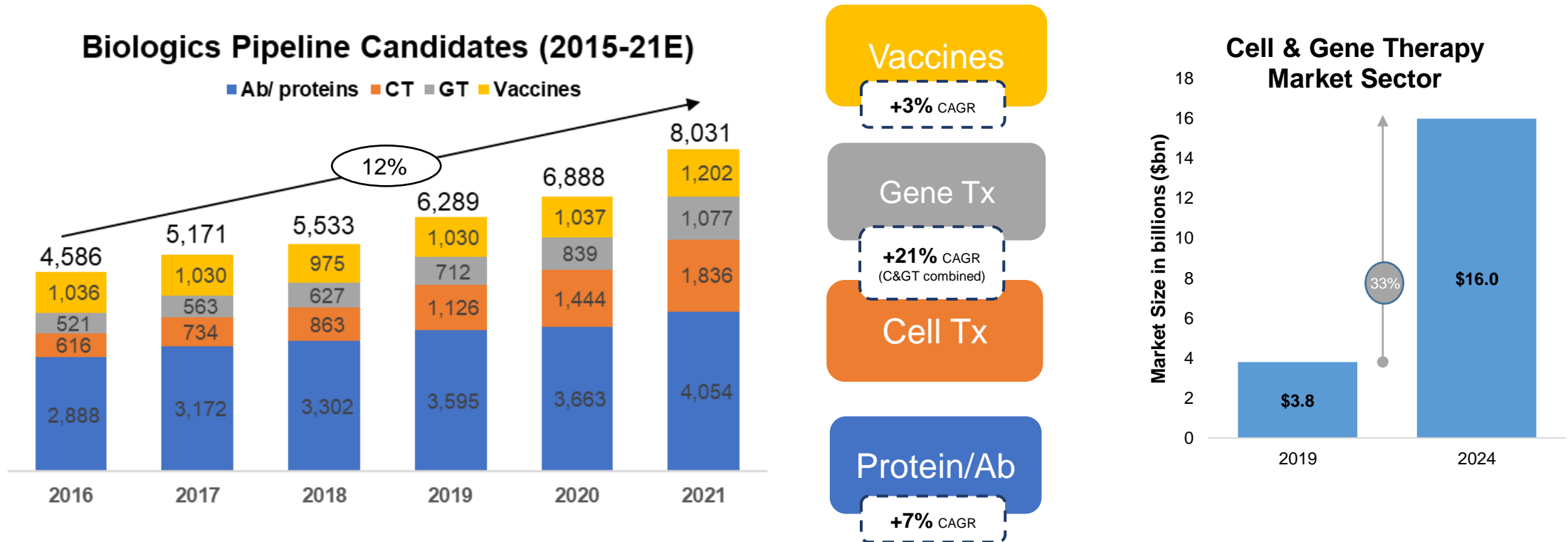
■ CRL Biologics Offering

■ CRL C&GT Offering Only



**Outsourced Market Sector for Current CRL Service Areas**  
**\$1.8B-\$2B<sup>(1)</sup>**

# Significant Growth Potential Driven by C&GT



**Overall biologics market is growing at least in the low-double digits,  
with C&GT projects growing at >20%**



# Biologics: Cell and Gene Therapy (C&GT) Offerings



## Analytical Support

- Develop, qualify, and validate testing methods required for product identity, purity, & potency
- New state-of-the-art technology platforms (e.g., ddPCR)



## Safety Testing

- Assure products are free of contamination from virus, microbial contaminants, or harmful process chemicals
- Rapid testing methods to achieve product release time for short shelf-life C&GT products



## Cell Bank Manufacturing

- Prepare & characterize the cell banks used in biologics manufacturing process
- Capability enhancements to accommodate storage for C&GT products



## Product Potency Testing

- State-of-the-art flow cytometry tools to develop & validate novel potency assays for C&GT products

# Strengths & Synergies with Cognate



## Key Strengths

- Comprehensive testing portfolio across the entire drug development pipeline through commercialization
- Global footprint with strong logistical coverage
- State-of-the-art technology platforms with competitive turnaround times



## Key Strengths

- Integrated provider of CGMP cell therapy, plasmid, and viral vector CDMO services
- Ability to serve all clinical and commercial phases
- Strong market reputation and brand recognition

## Key Synergies



With the growth in C&GT, clients are looking for end-to-end providers with a global footprint and a single point of contact for program management



More clients are requiring quality improvement in addition to scaling

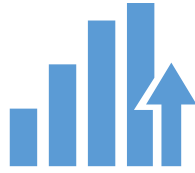


CDMO activities feed Biologics GMP testing pipeline



Harmonized testing and manufacturing strategy for optimal service offerings in response to new novel therapies

# Global Biologics Footprint Proximate to Clients



Global expansion, with capacity expansions in U.S. and Europe to accommodate robust client demand



Active in 45 countries, across 6 continents



~1,000 clients worldwide

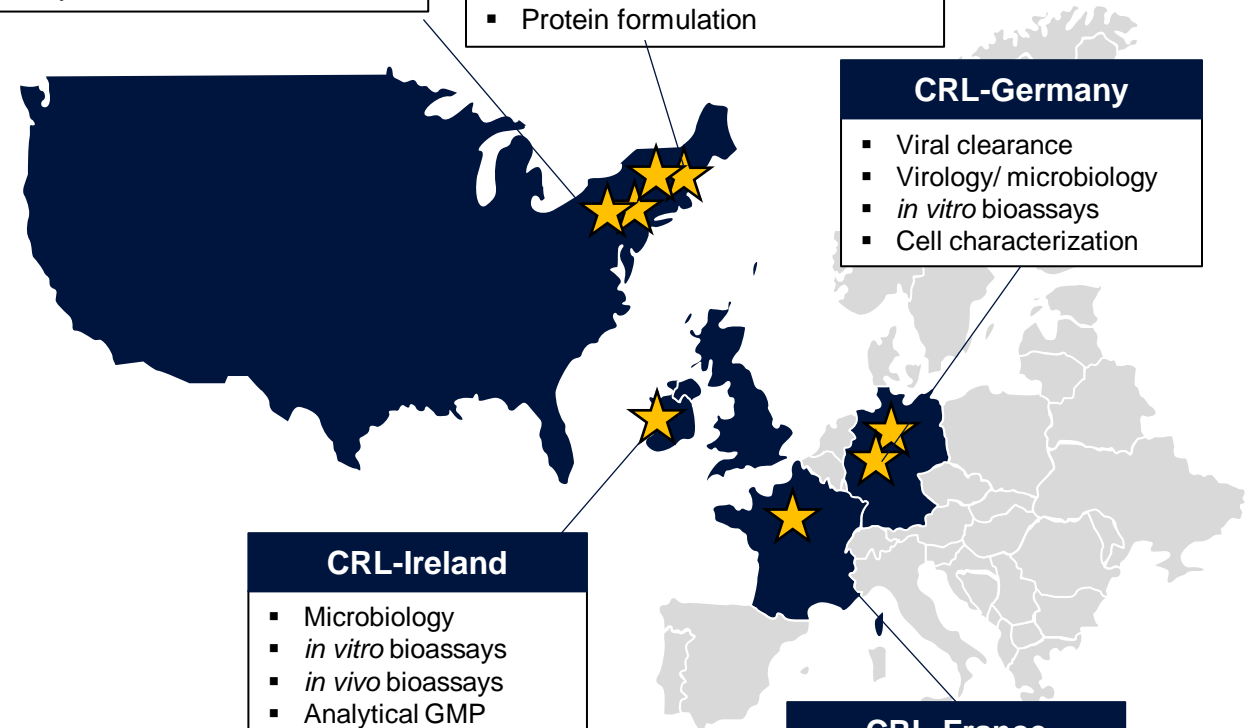
CRL-Pennsylvania
<ul style="list-style-type: none"><li>Cell banking/ characterization</li><li>Biosafety</li><li>Viral clearance</li><li>Analytical GMP</li></ul>

CRL-Massachusetts
<ul style="list-style-type: none"><li>Analytical GMP/ stability</li><li><i>in vitro</i> bioassays</li><li><i>in vivo</i> bioassays/ lot release</li><li>Protein characterization</li><li>Protein formulation</li></ul>

CRL-Germany
<ul style="list-style-type: none"><li>Viral clearance</li><li>Virology/ microbiology</li><li><i>in vitro</i> bioassays</li><li>Cell characterization</li></ul>

CRL-Ireland
<ul style="list-style-type: none"><li>Microbiology</li><li><i>in vitro</i> bioassays</li><li><i>in vivo</i> bioassays</li><li>Analytical GMP</li></ul>

CRL-France
<ul style="list-style-type: none"><li><i>in vivo</i> bioassays</li></ul>





# Biologics Growth Strategy

