



# Empowering Early Detection of Kidney Injury

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December 11, 2023

# Forward-Looking Statements

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**FDA Grants 510(k) Marketing Clearance for ProNephro  
AKI™ (NGAL) for Pediatric AKI Risk Assessment**



# ProNephro AKI™ (NGAL): Indications for Use

## Indications for Use:

Immunoassay for the in vitro quantitative determination of neutrophil gelatinase-associated lipocalin (NGAL) in **human urine.**

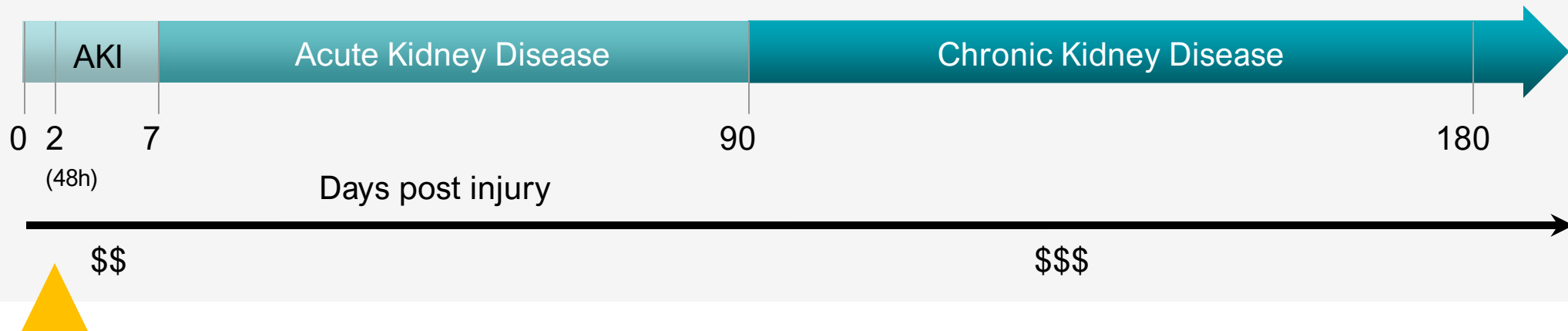
Determination of NGAL is intended to be used **in conjunction with clinical evaluation** in pediatric patients (**≥ 3 months to < 22 years**) without underlying kidney disease admitted to the intensive care unit (ICU) for the management of cardiovascular or respiratory compromise or who have had a solid organ or bone marrow transplant.

ProNephro AKI™ (NGAL) is intended to be used in the first 24 hours of ICU admission. In patients with low SCr levels, indicative of no acute kidney injury (AKI) or AKI Stage 1, the test can be used as an aid to identify patients at risk to develop moderate to severe acute kidney injury (Stage 2 to 3 AKI) 48 to 72 hours after the time of assessment. In patients with an elevated SCr level, indicative of Stage 2/3 AKI, the test can be used as an aid to identify patients at risk to have persistent moderate to severe acute kidney injury (Stage 2 to 3 AKI) 48 to 72 hours after the time of assessment.

**The particle-enhanced turbidimetric immunoassay is intended for use on the Roche cobas® c 501 clinical chemistry analyzer.**

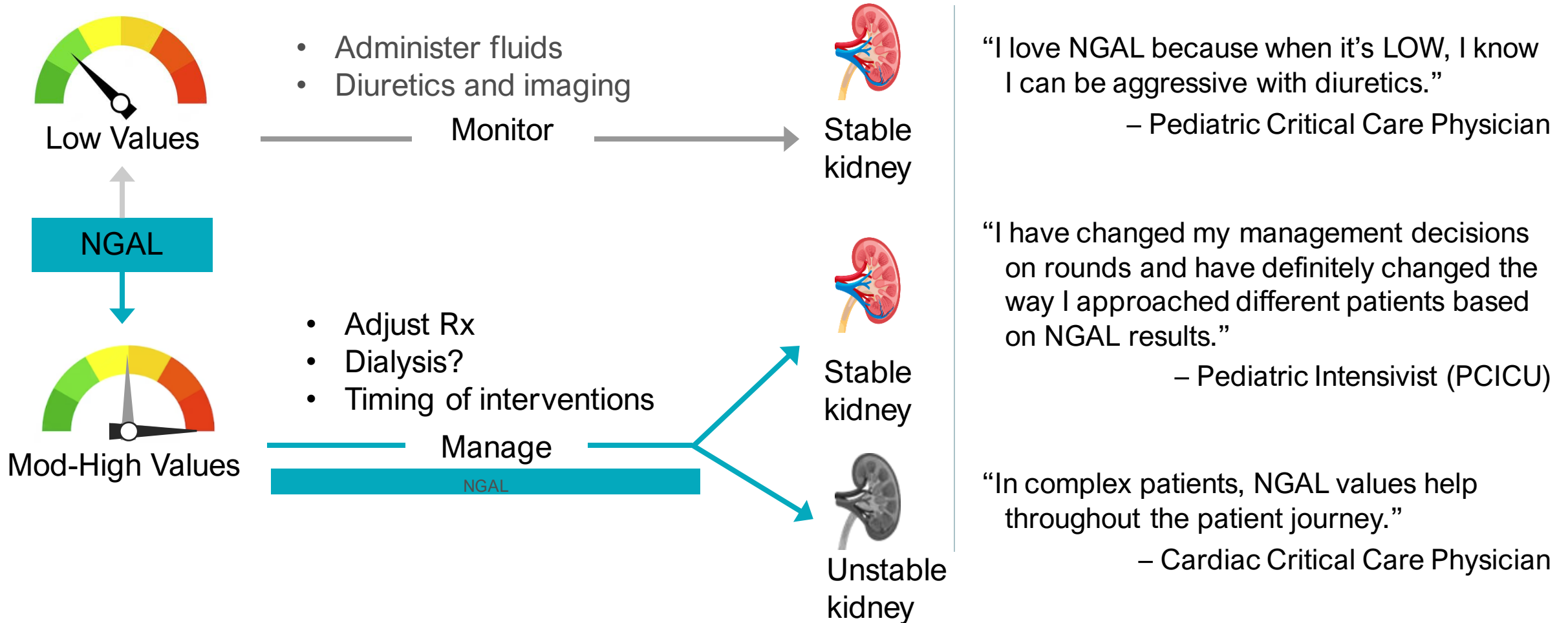
# Acute Kidney Injury (AKI) — An Unmet Clinical Need

- **AKI**, is an abrupt loss of kidney function that develops rapidly over a few hours or days.
- Symptoms may include decreased urinary output, swelling due to fluid retention, nausea, fatigue, and shortness of breath. **Often painless without symptoms.**
- **Difficult to diagnose.**
- **AKI can progress** to CKD (Chronic Kidney Disease), leading to a lifetime of dialysis and death.



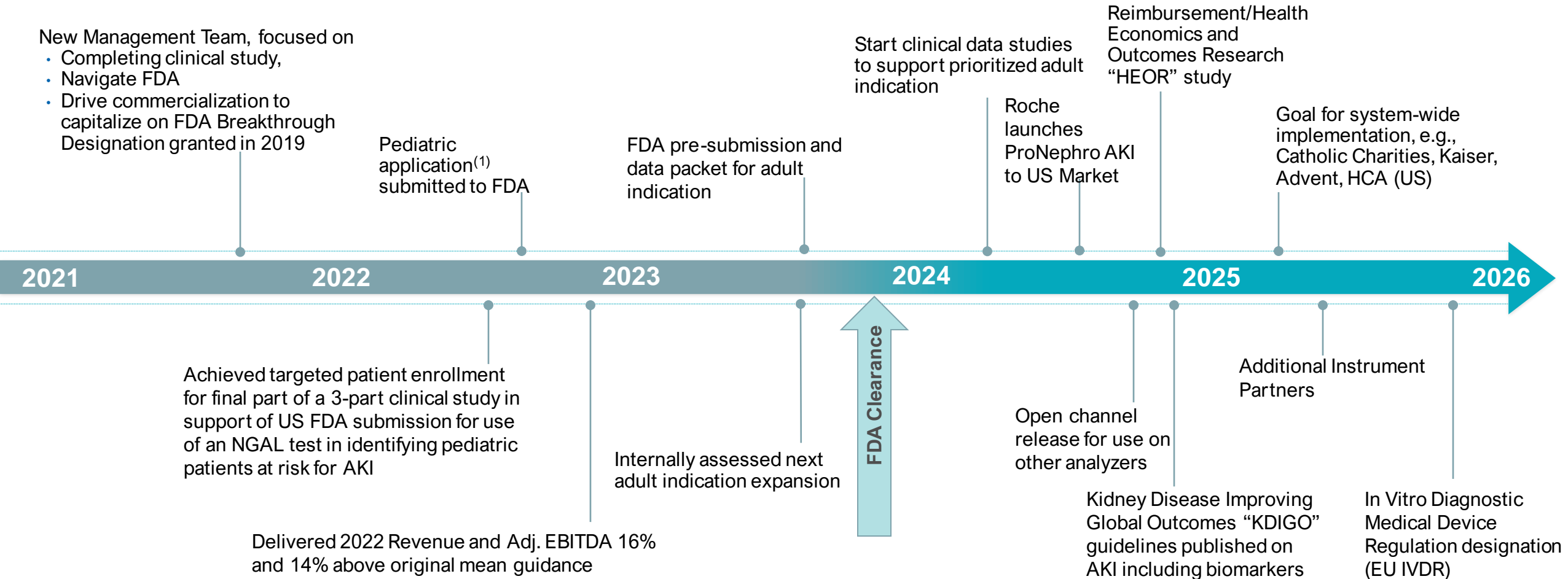
ProNephro AKI™ (NGAL)

# NGAL Values Actively Direct Interventions in Critical Care



When & why patients would be evaluated for AKI

# Track Record of Execution and Clear Commercial Roadmap

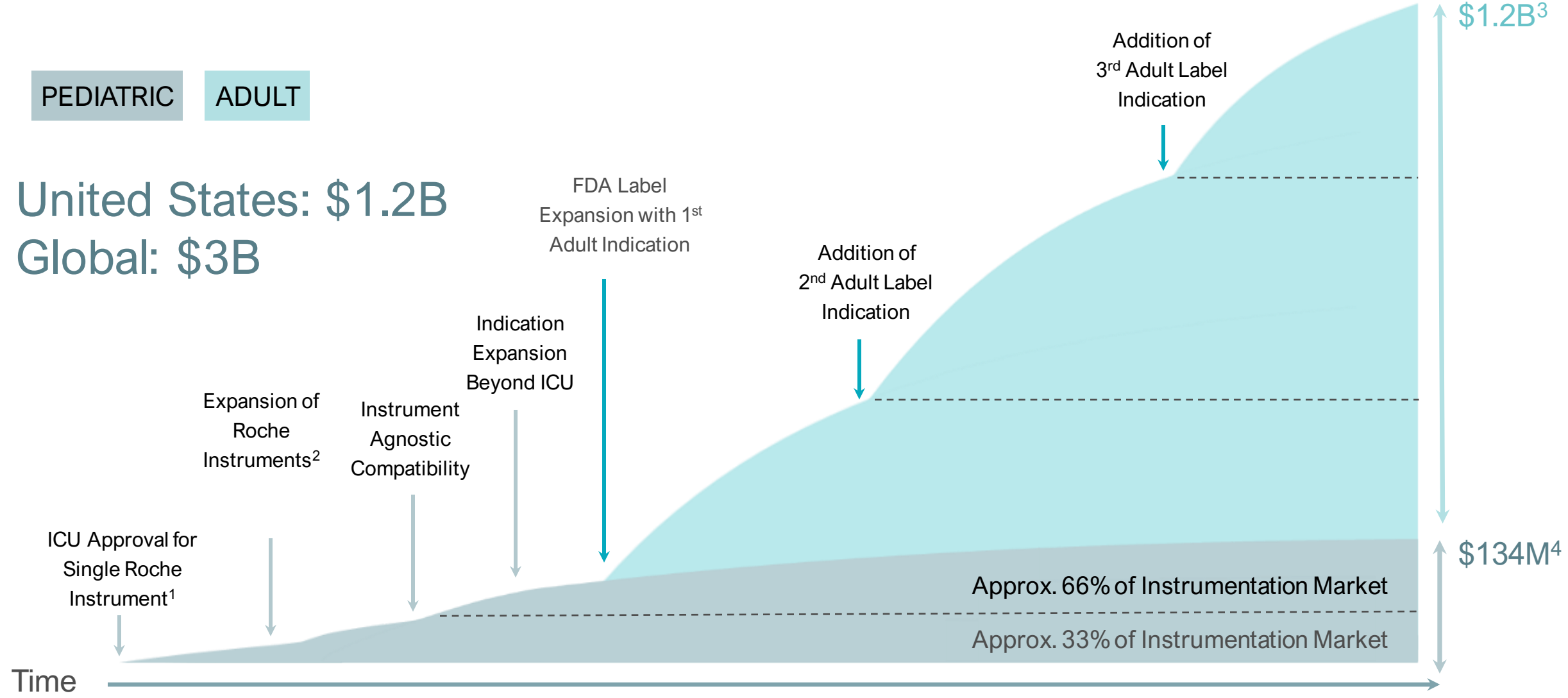


# US TAM Growth: Broadening Compatibility & Adult Label Expansion

TAM  
\$1.2B<sup>3</sup>

PEDIATRIC ADULT

United States: \$1.2B  
Global: \$3B



- 1 Roche \*c501 Instrument
- 2 Following subsequent CLIA filing to expand compatibility with expanded Roche family of Instruments
- 3 Combined Emergency Room, Cardiac Bypass Surgery, Cirrhosis, Kidney Transplant, Initiation/Liberation from Dialysis, etc.





**bioporto**  
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