

BIONICAL

Access Programs



ng Patient Outcomes

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exciting stuff

ing Patient Outcomes



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en is the right time?????

etting caught up in terminology

hanism that enables patients with an unmet medical need to be
ed with access to a medicine when they are unable to enter a clinical
when the drug is not commercially available in their country

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|-------------------|------------------------|
| nded Access | ✳ Compassionate Use |
| ed Patient Supply | ✳ Cohort Route |
| ial Access Scheme | ✳ Personal Importation |
| Trial Access | ✳ Managed Access |
| Access | ✳ Pre-approval Access |

Clinical Trial

Often confused as U.S. regulations lead to Expanded Access Programs looking very similar to a clinical trial.

E.g. outside the U.S. most countries do not require any protocol.

Commercial Launch

Companies often focus on U.S., E.U. 5, Rest of E.U., then RoW

exciting future challenges

