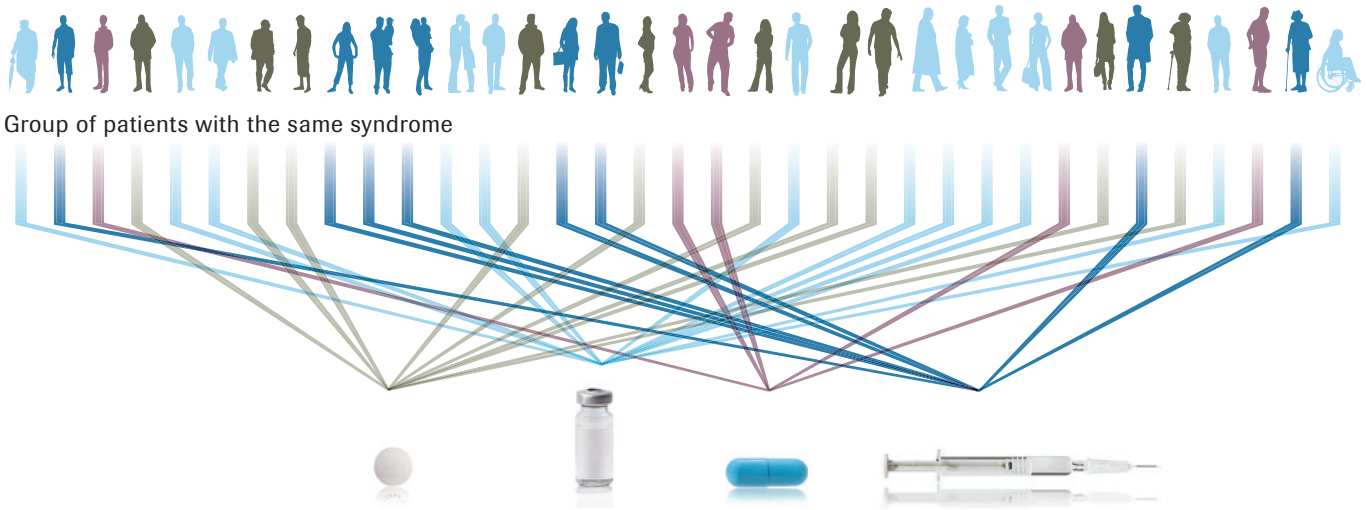
Bringing personalized healthcare to chronic hepatitis B (CHB) patients

Providing a tailored treatment approach for each patient

Patients do not always respond to therapy in the same way because different combinations of inherited or acquired risk factors can influence response. The personalized healthcare (PHC) approach exploits these differences to tailor treatments to different patient groups. Monitoring disease markers to determine treatment response allows selection of the optimal therapeutic strategy. In turn, this avoids unnecessary therapy and provides cost benefits for overburdened healthcare systems worldwide.

Roche is committed to developing PHC solutions, one of which is for patients with CHB. Worldwide, approximately 350 million people have CHB[1] and no single treatment will be suitable for them all. The ability to tailor treatment to each patient guarantees the best chance of a successful outcome.

Medicines are like suits – one size doesn't fit all



Group of patients with the same syndrome

Tailored treatment approaches for each patient

Response-guided therapy as an example of PHC in CHB

For patients with CHB there are currently two treatment options:[2–4]

- Long-term (potentially indefinite) therapy with nucleos(t)ide analogs (NAs)
- Finite therapy with IFN-based therapy, such as pegylated interferon α-2a (PEG-IFN; PEGASYS).

On-treatment monitoring of hepatitis B surface antigen (HBsAg) levels using the Elecsys HBsAg II quant assay can identify CHB patients who are likely to achieve sustained immune control after a finite course of PEGASYS therapy.

Hence, measuring of HBsAg levels at Week 12 or 24 of PEG-IFN therapy can help physicians determine the best management strategy for their CHB patients.[5,6]

✓ Patients who are identified as likely responders can be motivated to continue with PEGASYS therapy

✗ Stopping rules can be implemented in patients identified as non-responders to avoid unnecessary therapy and its associated costs and allow a change of therapeutic strategy.

Bringing response-guided therapy for CHB to the clinic

In patients with CHB, HBsAg cut-off levels, or defined changes in HBsAg levels, have been determined that identify patients who are likely, or unlikely to respond to PEGASYS therapy and treatment can be adjusted accordingly.[7-9]

HBeAg-positive CHB

Identify responders ✓ | **Identify non-responders** ✗

Week 12 – for patients infected with genotypes B and C[7]

≤20,000 IU/mL **HBsAg level** **>20,000 IU/mL**

Week 24 – for patients infected with all genotypes[8]

≤20,000 IU/mL **HBsAg level** **>20,000 IU/mL**

Motivate patient to continue PEGASYS therapy | **Stop PEGASYS/change strategy**

HBeAg-negative CHB

Identify responders ✓ | **Identify non-responders** ✗

Week 12 – for patients infected with all genotypes*[9]

Yes **HBsAg decline from baseline** **No**

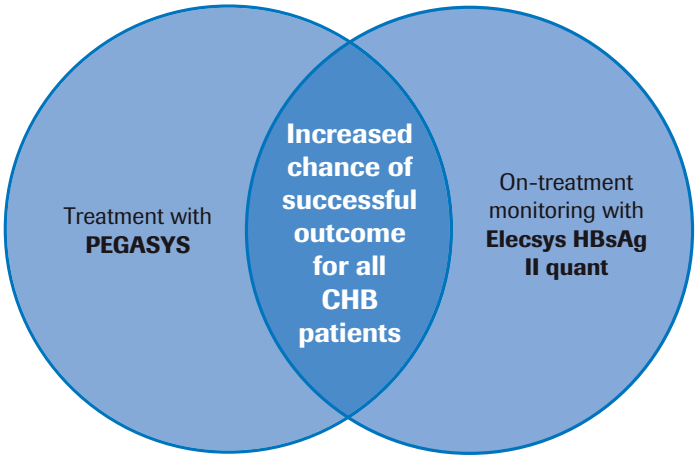
≥2 $\log_{10}$ IU/mL **HBV DNA decline from baseline** **<2 $\log_{10}$ IU/mL**

Motivate patient to continue PEGASYS therapy | **Stop PEGASYS/change strategy**

***but performs best for patients infected with genotype D**

Combining PEGASYS therapy and the Elecsys HBsAg II quant assay: increasing chances of a successful outcome for all CHB patients

The medical value of HBsAg quantification for monitoring response to PEG-IFN therapy has been recognized in recent updates of the EASL and APASL clinical practice guidelines for management of CHB[2,3] The strong partnership between finite PEGASYS therapy and the Elecsys HBsAg II quant assay enables a response-guided approach to be implemented to increase each individual's chance of a successful treatment outcome.



References

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